



Food and Drug Administration



**Global Unique Device Identification Database (GUDID)
Release 1.4, 1.5, 1.6.1 & 1.6.2**

**Health Level 7 (HL7) Structured Product Labeling (SPL)
Implementation Specification
Version 1.5**

Date: December 3, 2024

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INSTRUCTIONS TO READER

This is a technical document that provides instructions on how to implement the HL7 SPL standard for GUDID. The following content will be provided in a consistent manner within the document and/or the reader may be prompted by visual cues about the context or referenced information being presented in the document.

Document Content

In the document there are notations that are used to provide clarity to the subject matter. The following table provides visual cues that are used in the document.

Table 1: Legend of Symbols used in Document

Icon	Description
	Items to be careful to follow are indicated by the bubble with an exclamation inside.

When the document refers to XML components (e.g. elements and attributes) versus the concept that it represents, the text will take the following notation:

- XML elements and attributes
 - In narrative text, they will be Bold, Italicized text in Camel case, e.g., *ContextOfUse*
 - Within the XML, they will be shown as notated below for the XML Snippets.
- Concept without attribution to the model or message
 - Plain text with first letter capitalized as it is a defined concept, e.g., Context of Use

XML Snippets

The following figure indicates the color coding used in the XML snippets and any meaning that should be inferred by the samples.

Table 2: Legend for XML Snippets

Text Color	Description <i>Sample</i>
Teal	Schema components <i><?xml version "1.0" encoding="UTF-8"?></i>
Blue	XML notations <i>< = "></i>
Brown	XML element <i>id</i> <i>code</i>
Red	XML attribute <i>root</i> <i>extension</i>
Black	Value of the element or attribute <i>2.16.840.1.113883</i>



Note: XML editors may display these XML components differently, please use the legend above for XML presented in this document.

Required Schema Attributes

The GUDID HL7 SPL message contains attributes that have not been set to a fixed value to provide for future extensibility of the schema. When submitting a GUDID HL7 SPL submission, these attributes need to be sent in with the fixed value as specified in this document. The value for all schema attributes will be specifically stated for each element when required.

For example:

The *manufacturedProduct@classCode* value must be equal to “MANU” to pass schema validation. Any other value in this field may cause the schema validation to fail.

In the example above, the value for the *classCode* attribute should be “MANU”. In the future, this may be fixed in the schema, but for increased extensibility of the schema, it has not been constrained any further.

XML Elements Tables

A table has been provided for each element in the XML message. When elements have multiple element parts or attributes, they are provided in one table. When there are no attributes or values for an element, the cell is grayed out to indicate that no value is required in the XML message.

Table 3: Sample XML Element Table

Table Name: <element>

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	XPATH:			
<i>Business Rules</i>				

Table Name: Each table is named for the elements it is representing in the XML – i.e., <element> or <element 2>.

Element: Identifies the XML element

Attribute: Identifies the XML attribute

Cardinality: Provides information on how many times the element/attribute can be repeated in the XML message.

Value(s) Allowed/Examples: Identifies the values allowed using simple data types and any associated examples. References to controlled vocabulary will also be provided

Description/Instructions: Provides a description of the element or attribute

XPATH: Identifies the location of the data element or attribute in the XML.

Business Rules: Identifies any business rules that are in place for GUDID.

1. INTRODUCTION

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, the nation’s food supply, cosmetics, dietary supplements, and products that give off radiation; and for regulating tobacco products.

Section 226 of the FDA Amendments Act (FDAAA) of 2007 and Section 614 of the FDA Safety and Innovation Act (FDASIA) of 2012 amended the Federal Food, Drug, and Cosmetic Act to add section 519(f), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The Unique Device Identifier (UDI) Proposed Rule was published on July 10, 2012, followed by an amendment, published on November 19, 2012, modifying the implementation time frame for certain devices. In developing the proposed rule, FDA solicited input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives were incorporated as possible. The UDI Final Rule was published on September 24, 2013.

This document is intended to primarily to provide information about submitting data to the GUDID for device Labelers¹, specifically for the Health Level 7 (HL7)² Structured Product Labeling (SPL)³ submission option. The ‘GUDID Guidance for Industry and FDA Staff’ document, available at www.fda.gov/udi, serves as a precursor document and should be reviewed prior to this document. The GUDID Guidance provides more comprehensive information about GUDID, including the GUDID account structure and the Device Identifier (DI) record life cycle.

	It is very important for labelers to review and understand the material in the GUDID guidance document before delving into the GUDID HL7 SPL implementation specification files.
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Please note that database enhancements will continue, to improve user experience, build in better validation rules, and make other necessary changes as we “learn” from the initial roll-out and implementation. The FDA intends to periodically update this document to reflect system changes and enhancements.

¹ The UDI Final Rule (<http://www.fda.gov/udi>) defines labeler as “any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.”

² HL7’s mission is to provide messaging standards for interoperability, exchange, management, and integration of data that supports clinical patient care and the management, delivery, and evaluation of healthcare services. Visit www.hl7.org for more information

³ Structured Product Labeling (SPL) is a HL7 standard for the exchange of product information using extensible markup language (XML).

2. UNIQUE DEVICE IDENTIFIER (UDI)

The “unique device identifier” (UDI) will be created and maintained by device labelers based on global device identification standards managed by FDA-accredited Issuing Agencies⁴. A UDI will be required to appear on the label of every medical device and every device package, unless granted an exception. A UDI is composed of two parts:

- Device Identifier (DI) - a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device; and
- Production Identifier(s) (PI) – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device, unless excepted:
 - the lot or batch number within which a device was manufactured;
 - the serial number of a specific device;
 - the expiration date of a specific device;
 - the date a specific device was manufactured; and,
 - for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

Therefore, **UDI = DI + PI**.

The DI will serve as the primary key and can be used to look up information about the device in the GUDID.

3. GUDID -- BRIEF SYSTEM OVERVIEW

The GUDID serves as the repository of key device information. The GUDID contains ONLY the DI, which serves as the primary key to obtain device information in the database. PIs are not submitted to or stored in the GUDID; the GUDID will contain only production identifier flags to indicate which PI attribute(s) are on the device label, unless excepted.

The GUDID provides two options for submission of device identification information:

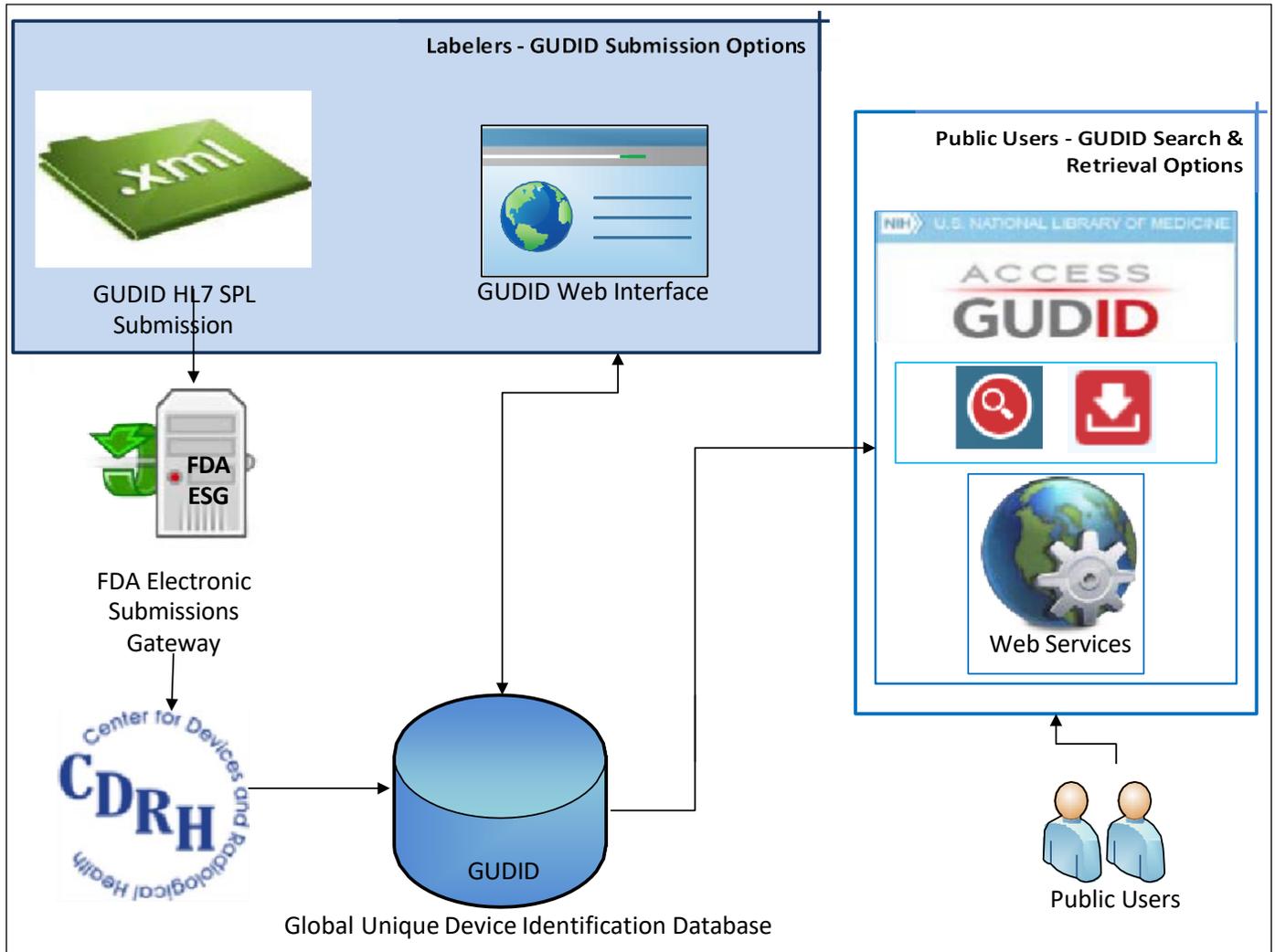
- 1) Submission of one Device Identifier (DI) record at a time via the secure GUDID Web Interface.
- 2) Submission of one DI Record per XML file via the HL7 SPL submission option using the FDA Electronic Submissions Gateway (ESG)

Published device information in GUDID will be available for public search and retrieval. Planned capabilities include ability to search for specific device information, full database download and web services.

Figure 1 provides a pictorial representation of the GUDID, as described above.

⁴ Refer to the UDI Final Rule (<http://www.fda.gov/udi>) for details on issuing agencies and their role in UDI assignment.

Figure 1: GUDID Submission Overview



Please refer to the GUDID guidance document, available on www.fda.gov/udi for more information on GUDID Web Interface submission option and GUDID Search and Retrieval.

3.1 FDA Electronic Submissions Gateway (ESG)

In order to submit GUDID HL7 SPL XML files securely to the FDA, organizations will be asked to utilize the FDA Electronic Submissions Gateway (ESG). The FDA ESG (also referred to as the ESG or the Gateway) provides the following:

- Enables the FDA to process regulatory submissions automatically.
- Functions as a single point of entry for the receipt and processing of all electronic submissions in a secure environment that complies with secure messaging standards.
- Serves as a conduit, or “highway,” along which submissions travel to reach their final FDA destination.
- Automatically routes submissions to the appropriate FDA Center or Office.

The Labeler will be responsible for establishing an account with the FDA’s Electronic Submission Gateway. For additional information about the ESG, please refer to the material available at

<http://fda.gov/ForIndustry/ElectronicSubmission/default.htm>

The FDA ESG allows two methods for transmitting electronic submissions, an Applicability Statement 2 (AS2) Gateway-to-Gateway connection or via a web interface, using the Web Trader application. The FDA

ESG allows multiple submission types for CDRH, and in order to route GUDID submissions correctly, please specify Center = CDRH and Submission Type = GUDID when using either ESG submission option to send GUDID submissions. If the GUDID HL7 SPL submission is sent to any other location, or sent as any other submission type, it may be rejected for incorrect file format.

For the AS2 Gateway-to-Gateway connection, the submission should follow these instructions:

- See the FDA ESG [Appendix G: AS2 Header Attributes](#); the “GUDID” submission type should be used for the “X-Cyclone-Metadata-FdaSubmissionType” in the MIME Header.

For Web Trader Interface, the submitter should follow these instructions:

- Choose Center = CDRH
- Choose Submission Type = GUDID

For either transmission option above, see Section 3.4 for Submission Packaging information – i.e., how to package the GUDID HL7 SPL submission.

Upon receipt of the HL7 SPL submission, the FDA ESG will route it to CDRH for processing and loading to the GUDID. Submitters will receive 3 Acknowledgements (ACK) as follows:

- ACK1 (also known as “Receipt” in the ESG Webtrader) will be sent by the FDA ESG and confirms the receipt of your submission. ACK1 will contain the Message Identifier specified by the submitter.
- ACK2 will be sent by the FDA ESG and indicates successful routing of your submission to CDRH. ACK2 will contain the Message Identifier (from ACK1) and will also contain a CoreID.
- ACK3 will be sent by GUDID and indicates the results of submission processing; successful transmissions will be noted, or, if there are any errors, submitters will be notified of errors, which needs to be fixed and submission resent via the FDA ESG.
 - The ACK3 XML Message contains the CoreID and information about your DI Record to include the Primary DI Number, Document version, processing date/time, the number of failed rules, and status of submission.
 - Please note that you may receive an HTML message if the submission type cannot be determined and/or the schema is invalid.
 - See ACK3 Message files included in the Implementation package for examples.

The three acknowledgments can be linked as follows:

- ACK1 Message ID --> ACK2 Message ID*
- ACK2 CoreID --> ACK3 CoreID

* ACK2 will contain the Message Identifier and a CoreID.

Contact the FDA ESG at ESGHelpDesk@fda.hhs.gov for issues/delays associated with ACK1 and or ACK2. If you have received the first two acknowledgements and not ACK3 within 48 hours, contact the FDA UDI Help Desk. For all issues with acknowledgements, always send either the message identifier (ACK1) and/or the CoreID (ACK2 and ACK3) and the DI number of the record in question. (Note: if there is a published outage, your submission will be processed when the system has been restored. Refer to the UDI Program website for FDA UDI Help Desk and System Status information at: www.fda.gov/udi).

3.2 GUDID HL7 SPL Submission Option

FDA\CDRH is a strong proponent of utilizing messaging standards and vocabularies in order to improve interoperability. GUDID will utilize HL7 SPL Draft Standard for Trial Use (DSTU) Release 5 along with standard vocabularies.

Labelers that choose this option to submit information to GUDID will first need to complete testing prior production GUDID submissions. Labelers need to–

- Review the ‘GUDID Guidance for Industry and FDA Staff’ document to understand GUDID account structure, and the DI record life cycle.
- Obtain a digital certificate and register with the FDA ESG for a test account. See Section 3.1. Detailed information is available on the ESG website at <http://www.fda.gov/esg>.
 - Note: existing ESG test accounts may be used for GUDID testing
- Complete FDA ESG testing as specified on their website.
- Request a GUDID test account by visiting <http://www.fda.gov/udi> and submitting a GUDID Account Inquiry. Indicate on the account request that you are asking for a test account. Please refer to Section 3.6 for information on testing.
- Upon completion of testing, you will need to obtain a production GUDID account to send your production GUDID submissions.

Note: Review the GUDID Guidance document to understand GUDID account structure and the recommended preparatory steps prior to requesting a GUDID account. The following information should be provided when requesting a GUDID Account:

- Labeler Organization DUNS Number – this DUNS number represents the labeler’s view of the highest corporate level in the labeler organization; it may be the headquarters DUNS number, or the parent DUNS number for the Labelers included in the GUDID account.
- Labeler Organization Name – this is used for verification purposes only; GUDID will obtain company name and address from the DUNS database.
- Regulatory Contact information – name, email, phone and physical address.
- Labeler DUNS for the GUDID Account – please note that in order to ensure data consistency the company name associated to the Labeler DUNS number should match the company name that appears on the device label. Ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement; however, labelers are encouraged to work towards this model for new products and when making changes to existing products as appropriate.
- Coordinator(s) Information – The Coordinator user role enables organizations to create Labeler Data Entry (LDE) user role, thereby enabling viewing of submitted DI records via the web interface option.
 - Contact information – name, email, phone
 - List of Labeler DUNS that is the responsibility of the Coordinator; if there are multiple Coordinators, please specify the DUNS that each Coordinator is responsible for in GUDID.
- Organizations may choose to use a third-party (contractor/vendor) to submit device information to GUDID. Third-party DUNS number(s) should be provided and associated with the specific Labeler DUNS so that the third-party can submit GUDID HL7 SPL submissions.

Note that GUDID account user contact information is used for internal FDA purposes only; this information is not made public.

Once FDA Staff receives the GUDID account request, the GUDID account will be created; Coordinator(s) will receive login information and a temporary password via a system generated email.

3.3 GUDID HL7 SPL Implementation Package

The GUDID HL7 SPL Implementation package includes all information necessary for the submission of DI Records to the GUDID using HL7 SPL XML. However, please note that it is very important to review the GUDID Guidance for Industry and FDA Staff document, available at www.fda.gov/udi, prior to delving into the HL7 SPL implementation package of files. The GUDID guidance provides more comprehensive information about GUDID, including the GUDID account structure and the Device Identifier (DI) record life cycle. It is very important for labelers and HL7 SPL xml submission solution providers to review and understand the material in the guidance document.

This document provides technical specifications and implementation information on the GUDID HL7 SPL file submission option.

Supporting files/documents (to be provided in a zip file) are referenced in the table below, yyyyymmdd specify the year, month and date the file was updated.

Document	File Name	Contents
GUDID Read Me First File	yyyyymmdd_GUDID_ReadMeFirst Release.xls	Provides a text description of all files related to the testing documents required for the GUDID implementation.
Implementation Guide	yyyyymmdd_GUDID_HL7SPL_Impl Spec.pdf	Provides the implementation details for GUDID HL7 SPL submission – i.e., all content included in this document
GUDID Controlled Vocabulary/Code Lists	yyyyymmdd_GUDID_SPLCodeList.xls or yyyyymmdd_GUDID_CV.xml	Contains Data Elements for SPL, Code Lists, OID List, Unit of Measure list and XPATHs.
GUDID Testing Requirements	yyyyymmdd_GUDID_TestCriteriaProduction.pdf	Provides the testing requirements for submission in the test FDA ESG and GUDID environments before gaining access to the production environment.
Sample GUDID submission sent by Labeler	yyyyymmdd_GUDID_HL7SPL_LabelerSample.xml (within the Samples Folder)	Provides a sample of the GUDID HL7 SPL submission submitted by a Labeler.
Sample GUDID submission sent by Third-Party	yyyyymmdd_GUDID_HL7SPL_ThirdPartySample.xml (within the Samples Folder)	Provides a sample of the GUDID HL7 SPL submission submitted by a Third-Party
ACK3 Sample Messages	yyyyymmdd_GUDID_ACK3_Samples folder contains: InvalidXML_ACK3.html FailedACK3.xml PassedACK3.xml	Provides example of passing and failed ACK3 messages for the GUDID.
GUDID Schema File	GUDIDHL7SPL.xsd	The production schema file as a flattened schema of the implementation schema files constrained from the HL7 SPL DSTU R5.

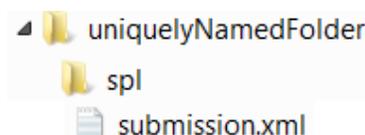
Document	File Name	Contents
GUDID HL7 SPL Submission Checklist	yyyymmdd_GUDIDHL7SPLSubmissionChecklist.pdf	Check list of process steps necessary to submit GUDID HL7 SPL production submissions.

3.4 Submission Package

The GUDID HL7 SPL Submission should be submitted via the FDA ESG. When submitting your GUDID HL7 SPL Submission the following specifications should be followed:

- Generate your GUDID HL7 SPL XML file.
- Name the SPL XML file “submission.xml”
- Validate your submission.xml file against the GUDID HL7 SPL schema prior to submission (see GUDIDHL7SPL.xsd, available in the GUDID HL7 SPL Implementation package of files). Submissions that are not in conformance with the GUDID HL7 SPL schema will be rejected with the message “Unable to parse XML”.
- Place the GUDID HL7 SPL Submission (named “submission.xml”) into a folder named “spl”. Place the folder named “spl” into another uniquely named folder, to create a folder hierarchy as shown below in Figure 2. The “spl” folder should contain ONLY ONE submission.xml file that is compliant with the provided schema and business rules. No additional files or folders should be included in either folder - please do not include multiple spl folders or multiple submission.xml files within the specified folder structure.

Figure 2: GUDID HL7 SPL Submission Folder Structure



	If the submission does not comply with the folder structure noted above or if there are any additional files or folders included, the submission may be rejected.
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- Send the entire folder, i.e., the uniquely named folder through the FDA ESG.
 - If you are using the ESG Web Trader, you will be able to browse for the folder name and attach it to the transmission. Please choose Center = CDRH, Submission Type = GUDID
 - If you are using an AS2 connection, it should be configured to send the archived and compressed folder directly (e.g., uniquelyNamedFolder.tar.gz). “GUDID” submission type should be used for the “X-Cyclone-Metadata-FdaSubmissionType” in the MIME Header, for more information, see the FDA ESG [Appendix G: AS2 Header Attributes](#). For information on creating tar files and compressing them for submission, please see: <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm334780.htm>

3.5 Versioning SPL Submissions

A GUDID HL7 SPL submission contains one and only one DI Record to optimize the processing of submissions. The initial DI Record establishes a DI Record in the GUDID database. After the initial submission is received, any updates must include the entire DI Record data – i.e., the SPL does not contain partial records or just the changes to the submission. Each time the submission is received, all of the business rules will be executed on the contents of the SPL submission. Some key items to consider in the implementation of GUDID HL7 SPL submissions:

- The entire DI Record must be sent each time, including but not limited to:
 - the elements and attributes that do not change must be resent without change;
 - the elements and attributes that changed shall be submitted in compliance with the business rules; and
 - any new elements shall be submitted in compliance with the business rules.
- The system will update the entire DI record with the new version if all of the business rules are passed (i.e., any changes must comply with all business rules before, during or after the grace period⁵)
 - Grace period does not apply – i.e., an unpublished DI Record with future DI Record Publish Date – the system will update the existing DI Record if the submitted changes meet all of the business rules. There are no restrictions on changing values of any data element.
 - During the grace period – i.e., a published DI Record with current DI Record Publish Date and during the grace period – the system will update the existing DI Record if the submitted changes meet all of the business rules.
 - After the grace period – i.e., a published DI Record that was published and the grace period has passed – the system will update the existing DI Record if the submitted changes meet all of the business rules and additional check against the grace period rules are met; and if changes relate to data elements that have a new DI Trigger, the submission will be rejected.

The GUDID HL7 SPL submission contains document information for the message that allows the GUDID system to link the initial submission to any subsequent updates. The following information must be provided for all submissions:

- The setID indicates the group of submissions that are related. Any updates to a DI Record must use the same setID value that was provided in the initial submission, especially if the primary DI number needs to be modified. If the setID is changed, an error in submission may result.
- The versionNumber must be incremented by 1; this will ensure that the setID and versionNumber are unique and that submissions are processed in the correct order and prevents older versions from overwriting newer versions.
- Once the DI record has been published, the DI record Publish Date cannot be changed. For DI record edits after the record is published, you must still provide a current DI record Publish Date as this is a required field; the value provided will be used to determine if the Publish Date is a current date. However, the original submitted Publish Date will not be changed in the record. See section 5.1.1.3, DI Record Publish Date for more information.

Note: A DI Record created with a particular submission option must use the same submission option to edit/update the record during the grace period. For example, if a DI Record is created via the GUDID Web Interface option, the DI Record can only be updated via the Web Interface during the grace period. After the grace period, the DI Record can be updated via the Web Interface and/or the HL7 SPL submission option.

⁵ GUDID Release 1.2.2, deployed on September 17, 2014, temporarily extended the DI record grace period to 30 calendar days to provide flexibility to users managing their DI record submissions in conjunction with the September 24, 2014 compliance date. We want to emphasize that this is a *temporary* change and will be updated in a future release.

In order to edit a web created record via HL7 SPL submission option, you need to assign a new setId and a new version number since a web created DI record will not have either of these values associated to it. We recommend doing thorough testing in the GUDID test environment prior to updating web created DI records via HL7 SPL submission option in the production environment.

Note that submitting via one option and editing via another submission option allows for the possibility of inconsistencies between the labeler's source data and GUDID submitted data. Labelers should develop and adhere to SOPs for data governance to maintain the quality of their device identification data. Our recommendation is for you to use the same submission option you used for initial submission for all updates/edits.

If there are additional questions about submitting a GUDID HL7 SPL submission, contact the FDA UDI Help Desk.

3.6 Pre-Production GUDID HL7 SPL Submission Testing

Labelers and/or third-parties using the GUDID HL7 SPL submission option must complete testing, which may include FDA ESG testing and GUDID HL7 SPL testing prior to production GUDID submission. The purpose of GUDID testing is to catch any issues early on, so once you transition to production submissions, there are no major problems due to improper formatting, incorrect values or validation failures in the submission. So we strongly recommend you perform thorough testing with realistic test data for all your devices, and ensure that all applicable GUDID data attributes and applicable business rules are tested. Please note the following with regards to GUDID HL7 SPL testing:

- First obtain a FDA ESG test account and complete necessary ESG testing as indicated on www.fda.gov/esg.
 - Existing FDA ESG test accounts may be used; ESG testing is not necessary for existing ESG test accounts. Please check www.fda.gov/esg or contact esghelpdesk@fda.hhs.gov if you have further questions.
- Upon completion of any necessary ESG testing, complete GUDID HL7 SPL testing.
 - Request a GUDID Pre-production (test) account, visit www.fda.gov/udi for more information.
 - Once a GUDID test account is established, you can begin GUDID HL7 SPL submission testing.
 - Complete thorough internal testing
 - Ensure that submitted test records are correctly loaded to GUDID by viewing those records via the GUDID web interface, either as Coordinator or Labeler Data Entry user.
 - Upon completion of your internal testing, complete the test scenarios as specified below. After you complete testing please send the following information to the [FDA UDI Help Desk](#):
 - For each test scenario:
 - CoreID⁶ and Primary DI Number
 - For Scenario 1a, 2a and 3a, GUDID Data Elements changed, value before change and value after change
 - Production ESG account:
 - If you have an existing ESG production account and intend to use it for GUDID production submissions, please let us know.
 - For labelers using third party submitters, please indicate whether a third-party ESG production account will be utilized for sending GUDID production HL7 SPL submissions

⁶CoreID is assigned by the FDA ESG for each submission, and is present on Ack2 and Ack3 messages.

- The FDA UDI staff will review the information and indicate next steps for production HL7 SPL submissions.

Note – Labelers using third-parties must complete the entire testing process as indicated below. Labeler is responsible for all data submitted to GUDID.

4. ESSENTIAL COMPONENTS OF THE GUDID HL7 SPL SUBMISSION

This section will provide a brief overview of the essential components of the GUDID HL7 SPL specification. The essential components include:

- Controlled Vocabulary
- OIDS and UUIDS
- Data Types
- GUDID HL7 SPL XML Schema
- GUDID HL7 SPL XML Message



Note to Implementers: *The schema does not include the business rules that need to be dynamic to the process. The business rules outlined in the subsequent sections should be handled by any system generating the XML message.*

4.1 Controlled Vocabularies

GUDID makes extensive use of controlled vocabularies. The information in the following sub-sections will outline the controlled vocabulary used to implement HL7 SPL for GUDID. There are several different authoritative sources for the controlled vocabulary, which include FDA, Unified Code of Units of Measure (UCUM) and the Global Medical Device Nomenclature (GMDN)⁷. All controlled vocabulary is provided in a separate XML file.



Note to Implementers: *The controlled vocabulary required by the HL7 SPL standard enables system to system communications and is not always the ideal way to display concepts in a system graphical user interface (GUI). Be cautious not to apply the technical codes in the GUI, instead use the business friendly terms.*

4.2 OIDS and UUIDS

There are two types of unique identifiers, Object Identifiers (OIDs) and Universally Unique Identifiers (UUIDs).

4.2.1 Object Identifiers

An OID is a sequence of numbers that uniquely identify an object and represent a hierarchically-assigned namespace. OIDs are formally defined using the International Telecommunications Union ASN.1 standard⁸. OIDS are represented as follows:

- Example – An OID is a string of digits separated by periods: 2.16.840.1.113883

⁷ Global Medical Device Nomenclature (GMDN) is a system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency. Visit: <http://www.gmdnagency.com/default.aspx>.

⁸ International Telecommunication Union, x680: Information technology – Abstract Syntax Notation One (ASN.1): Specification of basic notation

The list of named branches is as follows: {joint-iso-itu-t(2) country(16) us(840) organization(1) hl7(113883)}.

In the GUDID HL7 SPL submission, OIDs will be used to provide the codeSystem value for each element that requires a code. Each required element with a code will indicate when an OID should be provided. For example, the XML Snippet below illustrates the code element with a code (C101716 is the code value for a GUDID Submission) and codeSystem (2.16.840.1.113883.3.26.1.1 is the OID for the nciThesaurus code system):

```
<code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

For specific OIDs used in the GUDID implementation, please refer to the GUDID Code List documents.

4.2.2 Universally Unique Identifiers

A UUID is a hexadecimal number in the form of 8-4-4-4-12, including 32 characters and 4 hyphens⁹. UUIDs are formally defined by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. UUIDs are represented as follows:

- String of characters separated by hyphens: 36589652-7894-6589-3256-321852697531

In the GUDID HL7 SPL Submission, UUIDs will be used for any instance identifier root attribute value. Each required element with an identifier (e.g., id or code) will indicate when a UUID should be provided. For example, the XML Snippet below illustrates the id@root attribute for the SPL Submission that includes a globally unique value (760ae98c-eada-4678-90f4-fe97232292ce) for an identifier – e.g., document identifier:

```
<id root="760ae98c-eada-4678-90f4-fe97232292ce"/>
```

4.3 Data Types

Data Types of GUDID attributes are another essential component of the GUDID HL7 SPL specification. In order to provide all of the information required in the HL7 SPL message, the data types are represented as additional elements and attributes in the XML. The data type for the elements and attributes are as follows:

- Alpha – allowing only alpha characters to be used (e.g., FDA product code “IRT”)
- Alphanumeric – allowing alpha, numeric and special characters¹⁰ to be used in a string. XML should follow W3C standards for alphanumeric values.

GUDID HL7 SPL submissions only allow for UTF-8 character set. When adding special characters to xml, you need to use decimal or hex forms of the ISO Latin codes. More information can be found here: http://www.w3schools.com/charsets/ref_html_utf8.asp. Look under “C1 Controls and Latin 1 Supplement”, http://www.w3schools.com/charsets/ref_utf_latin1_supplement.asp We recommend you please fully test the special characters you plan to submit before submitting it in the production environment.

- Numeric – only allows numeric characters (e.g., 0 through 9.E+/-) to be used in a string for integers and real numbers.
- Boolean: allows a true or false value to be provided.
- nullFlavors: these are used when required values need to be left blank. Null flavors are based on HL7 Messaging standard.¹¹

⁹ International Telecommunication Union, x667: Information technology – Open Systems Interconnection – Procedures for the operation of OSI Registration Authorities: Generation and registration of Universally Unique Identifiers (UUIDs) and their use as ASN.1 object identifier components

¹⁰ Only UTF-8 character set is allowed.

4.4 GUDID HL7 SPL XML Schema

The HL7 SPL XML Schema will be provided as a flattened schema file with all the necessary schema files for GUDID implementation.

4.5 GUDID HL7 SPL XML Message

The following GUDID HL7 SPL message components are based on HL7 Version 3 SPL DSTU Release 5. The information for each element is provided in discrete sections. The following table provides a breakdown of the SPL XML structure with the relevant elements presented in this document.

Table 4: XML Structure

XML Structure
<p>The XML starts with administrative information about the XML file, including the XML version and encoding found in the XML.</p> <p>The Document element contains information about the GUDID Record and relates to the author.assignedEntity, which provides information about the Labeler.</p>
<pre> <?xml version="1.0" encoding="UTF-8"?> <document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 ../SPL.xsd"> <id root="80c7aca6-9307-4722-aa63-c40ef1fd6f36"/> <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/> <effectiveTime xsi:type="TS" value="20120531"/> <setId root="57863671-1527-4e51-b26b-3065a868d949"/> <versionNumber value="1"/> <author> <assignedEntity> <representedOrganization> <assignedEntity1> <code code=""/> <representedOrganization> </representedOrganization> </assignedEntity1> </representedOrganization> </assignedEntity> </author> </pre>
<p>StructuredBody contains the product information for a DI Record.</p> <p>ManufacturedProduct element contains the key information about the medical device product.</p> <p>AsIdentifiedEntity elements contain information about the product's model/version number and any other identifying value that may not be globally unique. (Note: this element can be repeated as many times as necessary)</p> <p>AsSpecializedKind elements contain information about the classification of the medical device in either the GMDN code or FDA Product code system. (Note: this element can be repeated as many times as necessary)</p> <p>asEquivalentEntity elements contain information about the medical device that are considered alternative identifiers to the primary device identifier. This includes secondary DI, direct marking DI and unit-of-use DI values. (Note: this XML element can be repeated as many times as necessary, but the cardinality of each data element requires conformance – e.g., you can only provide one direct marking or unit-of-use device identifier.)</p> <p>asContent elements contain information about the base packaging, device count and any packaging configurations (and their DI). (Note: the containerPackagedProduct element can be repeated as many times as necessary)</p> <p>subjectOf elements contain one of the following types of data: approval, marketing act, document author and device</p>

¹¹ Currently, nullFlavors are not used in the GUDID HL7 SPL submission.

XML Structure

characteristics.

```
<component>
<structuredBody>
<component>
  <section>
    <id></id>
    <subject>
      <manufacturedProduct>
        <manufacturedProduct>
          <code></code>
          <name></name>
          <desc></desc>
          <asIdentifiedEntity>
            <id></id>
            <code></code>
          </asIdentifiedEntity>
          <asSpecializedKind>
            <generalizedMaterialKind>
              <code></code>
            </generalizedMaterialKind>
          </asSpecializedKind>
          <asEquivalentEntity>
            <code></code>
            <definingMaterialKind>
              <code></code>
            </definingMaterialKind>
          </asEquivalentEntity>
          <asContent>
            <quantity>
              <numerator></numerator>
              <denominator></denominator>
            </quantity>
            <containerPackagedProduct>
              <code></code>
              <name></name>
              <capacityQuantity></capacityQuantity>
              <asManufacturedProduct>
                <subjectOf>
                  <marketingAct>
                    <effectiveTime></effectiveTime>
                  </marketingAct>
                </subjectOf>
              </asManufacturedProduct>
            </containerPackagedProduct>
          </asContent>
        </manufacturedProduct>
      </subjectOf>
      <document>
        <author>
          <assignedEntity>
            <representedOrganization>
          </representedOrganization>
        </author>
      </document>
    </subjectOf>
    <subjectOf>
      <approval></approval>
    </subjectOf>
```

XML Structure

```
<marketingAct>
  <code></code>
  <effectiveTime></effectiveTime>
</marketingAct>
</subjectOf>
<subjectOf>
  <characteristic>
    <code></code>
    <value xsi:type="CD"></value>
  </characteristic>
</subjectOf>
</manufacturedProduct>
</subject>
</section>
</component>
</structuredBody>
</component>
</document>
```

5. GUDID HL7 SPL SUBMISSION

The sections below provide implementation details for each of the elements in the GUDID HL7 SPL submission.

5.1 GUDID HL7 SPL XML File

The following section outlines the implementation specific rules for creating a GUDID HL7 SPL submission that will be compliant with the GUDID HL7 SPL schema and GUDID business rules. The content is organized by the order of the elements as they appear in the XML file, see Section 4.5.

5.1.1 SPL Document

The *document* element includes specific information about the GUDID HL7 SPL submission, to include required schema attributes (e.g., *xmlns*, *xmlns:xsi* and *xsi:schemaLocation*), a unique identifier of the SPL submission (*id@root*), a document type code to indicate that the HL SPL submission is a GUDID submission, the publish date of the Device Identifier (DI) record, and a versioning set identifier and version number to maintain the GUDID submission over time. Additional details on the following XML elements are provided below – *document.id*, *document.code*, *document.effectiveTime*, *setID* and *versionNumber*.

The following is an example of the XML section related to the GUDID Submission information:

```
]<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:hl7-org:v3 GUDIDSPL.xsd">
  <id root="851a3cb5-02ac-4649-9219-573f612a1f65"/>
  <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <effectiveTime xsi:type="TS" value="20130906"/>
  <setId root="9890b7f5-26d2-4988-9512-d8b2ecae6ff4"/>
  <versionNumber value="1"/>|
```

5.1.1.1 GUDID Submission Identifier (*document.id*)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description <i>Instructions</i>
<i>id</i>		1..1		This is the container element for the GUDID submission identifier.
	<i>Root</i>	1..1	<i>UUID</i>	This is a globally unique identifier for the GUDID submission.
	XPATH: /document/id/@root			
<i>Business Rules</i>	<ul style="list-style-type: none"> • The <i>id@root</i> should always be globally unique and will be validated for its uniqueness for each GUDID submission. Do not reuse document identifiers even if resending a submission after a submission failure. • If the <i>id@root</i> is found in the system, the GUDID submission will be rejected. All transactions are logged – i.e., even failed submissions are tracked. 			

5.1.1.2 Type of Submission (document.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the type of GUDID submission.
	<i>Code</i>	1..1	Alphanumeric C101716	This is the <i>code</i> for the type of document being sent via the XML Message.
	XPATH: /document/code/@code			
	<i>codeSystem</i>	1..1	OID 2.16.840.1.113883.3. 26.1.1	This is the unique identifier for the <i>codeSystem</i> associated with the code attribute.
XPATH: /document/code/@codeSystem				
<i>Business Rules</i>	<ul style="list-style-type: none"> The <i>code</i> attribute must have the value of “C101716”. If the value is different, the GUDID submission will be rejected as a submission with an invalid document code. Note: no other processing or validation will be completed if the code is incorrect. 			

5.1.1.3 Device Identifier (DI) Record Publish Date (document.effectiveTime)

The DI Record Publish date indicates the date the DI Record is published and made available via public search. The following XML snippet includes the elements and attributes required for the DI Record Publish date:

```

<document xmlns="urn:hl7-org:v3" xmlns:xsi="
http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3
GUDIDSPL.xsd">
  <id root="1zgb4a95-dba1-f5a7-1584-1740n3aa7s8i"/>
  <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <effectiveTime xsi:type="TS" value="20131108"/>
  <setId root="1zt4r2ja-gd14-1767-2584-18aef130a829"/>
  <versionNumber value="1"/>

```

5.1.1.3.1 *DI Record Publish Date (document.effectiveTime)*

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>				
<i>effectiveTime</i>		1..1		This is the container element for the DI Publish date.				
	<i>Value</i>	1..1	Date Format YYYYMMDD e.g., "20111016"	This is the publish date value for the DI Record.				
XPATH: /document/effectiveTime/@value								
<i>Business Rules</i>	The date must follow the format YYYYMMDD.							
	The date must be a current or future date (i.e., >=today, it cannot be a date in the past), otherwise the submission will be rejected.							
	If the publish date is today's date (current), the DI Record will be published in the GUDID immediately. Once the DI Record is published, the grace period begins. The grace period is seven ¹² calendar days and starts the day after the DI Record is published.							
	If the publish date is in the future, the DI Record will remain <u>unpublished</u> until the DI Record Publish date is reached. Note: An unpublished record does not have a grace period, and it can be edited unlimited number of times until the DI Record Publish Date has been reached.							
	We have allowed for a seven day ¹³ window to allow for internal processing, so current date cannot be a date greater than seven days in the past, or a future date. For example:							
		<table border="1"> <thead> <tr> <th>Current Date</th> <th>Publish Date can be any of these dates</th> </tr> </thead> <tbody> <tr> <td>Wednesday, October 8, 2014</td> <td> Wednesday, October 8, 2014 Tuesday, October 7, 2014 Monday, October 6, 2014 Sunday, October 5, 2014 Saturday, October 4, 2014 Friday, October 3, 2014 Thursday, October 2, 2014 Wednesday, October 1, 2014 </td> </tr> </tbody> </table>			Current Date	Publish Date can be any of these dates	Wednesday, October 8, 2014	Wednesday, October 8, 2014 Tuesday, October 7, 2014 Monday, October 6, 2014 Sunday, October 5, 2014 Saturday, October 4, 2014 Friday, October 3, 2014 Thursday, October 2, 2014 Wednesday, October 1, 2014
Current Date	Publish Date can be any of these dates							
Wednesday, October 8, 2014	Wednesday, October 8, 2014 Tuesday, October 7, 2014 Monday, October 6, 2014 Sunday, October 5, 2014 Saturday, October 4, 2014 Friday, October 3, 2014 Thursday, October 2, 2014 Wednesday, October 1, 2014							
If there is a date other than the current date, or a date that does not fit within seven day timeframe as shown above, the DI record will be rejected. If a DI Record needs to be unpublished, the Labeler must contact the FDA UDI Help Desk for assistance.								
Note: Once the DI Record has been published, the DI Record Publish Date cannot be changed. For DI record edits after the record is published, you must still provide a DI Record Publish Date as this is a required field; the value provided will be used to determine if the submission is submitted with the current date.								

¹² GUDID Release 1.2.2, deployed on September 17, 2014, temporarily extended the DI record grace period to 30 calendar days to provide flexibility to users managing their DI record submissions in conjunction with the September 24, 2014 compliance date. The grace period duration may be adjusted in a future release depending on usage and lessons learned.

5.1.1.4 GUDID Submission Versioning Set Identifier (*document.setId*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>setId (1..1)</i>		1..1		This is the container element for the versioning set identifier.
	<i>root</i>	1..1	UUID	This is the unique identifier used to track a document and its versions.
XPATH: /document/setId/@root				
<i>Business Rules</i>	<ul style="list-style-type: none"> • The <i>setId</i> element is the attribute used to keep updates linked to the initial UDI submission. This value will be unique for a DI Record. • For initial GUDID submissions the <i>setId</i> must be unique; if the <i>setId</i> is already in the system, the submission will be rejected. • For all submission updates, before or after the grace period, the <i>setId</i> would already be in the system, and should be used with the <i>versionNumber</i> (see below) incremented by one. If the <i>setId</i> is changed, the submission may be rejected if the Device Identifier is associated with a different <i>setId</i>. • For first time after-grace-period-edits to records initially entered via the GUDID Web Interface, please provide a new <i>setId</i> since web entered records will not have a <i>setId</i>. 			

5.1.1.5 GUDID Submission Version Number (*document.versionNumber*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>versionNumber (1..1)</i>		1..1		This is the container element for the GUDID submission version number.
	<i>value</i>	1..1	Integer <i>e.g., 1, 2, 3</i>	The <i>value</i> attribute provides the version of document that is being sent in the message.
XPATH: /document/versionNumber/@value				
<i>Business Rules</i>	<ul style="list-style-type: none"> • The value attribute should increment by one for each update. Note that you must increment the <i>versionNumber</i> even if resending a submission after a submission failure. • For first time after-grace-period-edits to records initially entered via the GUDID Web Interface, please provide a new <i>versionNumber</i> since web entered records will not have a <i>versionNumber</i>. • The combination of <i>setId</i> and <i>versionNumber</i> shall be unique for the DI Record (i.e., for that primary DI, the combination should not already exist in the database) 			

5.1.2 Submitter

Device information can be submitted to the GUDID by either labelers or third-parties. For more information on using third-parties, please see GUDID guidance document, GUDID Accounts section, available on www.fda.gov/udi.

¹³ Note that the seven-day processing window may be changed in the future.

Each GUDID HL7 SPL xml submission must indicate the author of the document, i.e., the document sender.

- Labeler as the sender of the HL7 SPL xml submission – must use the Labeler DUNS number. ***Please do not use the organization DUNS number to indicate the “sender”.*** The DUNS number provided here must be part of the GUDID account as Labeler DUNS.
- Third-party as sender of the HL7 SPL xml submission – must use the third-party DUNS number. This should be provided during GUDID account request to ensure the third-party is associated to the GUDID account.

As indicated earlier, please refer to the GUDID guidance document for more information on GUDID account structure, DUNS numbers and using third-parties.

During HL7 SPL submission processing, the “sender” is authenticated. Note: Once the DI Record has been published, the DI Record Publish Date cannot be changed. For DI record edits after the record is published, you must still provide a DI Record Publish Date as this is a required field; the value provided will be used to determine if the submission is submitted with the current date.

If the sender is not associated to the GUDID account, i.e., the Labeler DUNS or the third-party DUNS is not associated to the account, the entire submission will be rejected; the error message will state that that the submitter is not authorized to send GUDID submissions for the Labeler. (See Section 3.2 for information about the Labeler DUNS and Company Name of the medical device product).

The following XML Snippet includes the elements and attributes required for the Labeler:

```
<author>
  <assignedEntity>
    <representedOrganization>
      <assignedEntity1>
        <code code="C101684" codeSystem="2.16.84.1.11388.3.2.4.1.2" codeSystemName="DUNS" />
        <representedOrganization>
          <id root="1.3.6.1.4.1.519.1.1" />
        </representedOrganization>
      </assignedEntity1>
    </representedOrganization>
  </assignedEntity>
```

Note: The code value provided is to indicate that the Labeler Organization is the sender of the document.

5.1.2.1 Labeler Organization
(author.assignedEntity.representedOrganization.assignedEntity1.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Code		1..1		The code element is the container for the identification of the type of submitter for the GUDID submission.
	Code	1..1	Alphanumeric <i>C101684</i>	This is the code for the type of submitter for a GUDID submission, in this case, the Labeler Organization.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101684"]			
	codeSystem	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the unique identifier for the codeSystem associated with the code attribute.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code/@codeSystem			
Business Rules	<ul style="list-style-type: none"> The code attribute must have the value of “C101684” if the submitter is the Labeler Organization. See Section 5.1.2.2.1 if the sender is a third-party. 			

5.1.2.1.1

DUNS Number for Labeler – Labeler DUNS Number (author.assignedEntity.representedOrganization.assignedEntity1.representedOrganization.id)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Id</i>		1..1		The id element is the container element for the DUNS number associated with the submitter of the GUDID Submission
	<i>Root</i>	1..1	DUNS OID <i>1.3.6.1.4.1.519.1</i>	This is a globally unique identifier for the DUNS
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@root			
	<i>Extension</i>	1..1	DUNS Number <i>e.g., 123456789</i>	This is the assigned DUNS number.
XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@extension				
<i>Business Rules</i>	<p>The <i>root</i> attribute should provide the DUNS OID. The <i>extension</i> attribute should provide a 9-digit value for the DUNS number. The <i>id@extension</i> will be used to pull the Company Name from the D&B DUNS link database.</p> <p>During submitter authentication, the DUNS number provided here will be checked against the Labeler DUNS. See Section 5.1.6.3 for Labeler DUNS for the medical device, i.e., the labeler associated to the DI record. In this case, the Submitter and Labeler shall be the same.</p>			

5.1.2.2 Third-Party Organization

The following XML Snippet includes the elements and attributes required for Third-Party:

```

<author>
  <assignedEntity>
    <representedOrganization>
      <assignedEntity1>
        <code code="C101710" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <representedOrganization>
          <id root="1.3.6.1.4.1.519.1" extension="123456789"/>
        </representedOrganization>
      </assignedEntity1>
    </representedOrganization>
  </assignedEntity>

```

[Note: The code value provided is to indicate that the Third-Party is the sender of the document.]

5.1.2.2.1

**Third-Party
(author.assignedEntity.representedOrganization.assignedEntity1.code)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Code		1..1		The code element is the container for the identification of the type of submitter for the GUDID submission.
	code	1..1	Alphanumeric <i>C101710</i>	This is the code for the type of submitter for a GUDID submission.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101710"]			
	codeSystem	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the unique identifier for the codeSystem associated with the code attribute.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code/@codeSystem			
Business Rules	<ul style="list-style-type: none"> The code attribute must have the value of “C101710” if the submitter is a Third-party organization. 			

5.1.2.2.2

**DUNS Number for Third-Party – Third-Party DUNS Number
(author.assignedEntity.representedOrganization.assignedEntity1.representedOrganization.id)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Id		1..1		The id element is the container element for the DUNS number associated with the submitter of the GUDID Submission.
	root	1..1	<i>DUNS OID</i> <i>1.3.6.1.4.1.519.1</i>	This is an organization unique identifier for the DUNS.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@root			
	extension	1..1	DUNS Number e.g., 123456789	This is the assigned DUNS number.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@extension			

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Business Rules</i>				<p>The root attribute should provide the DUNS OID. The extension attribute should provide a 9-digit value for the DUNS number. The id@extension will be used to pull the Company Name from the D&B DUNS link database.</p> <p>During submitter authentication, the DUNS number provided here will be checked against the DUNS number for the Labeler DUNS. See Section 5.1.6.3 for Labeler DUNS for the medical device. In this case, the Submitter is Third-Party. The third-party DUNS must be associated to the appropriate GUDID Account and the Labeler DUNS submitted in 5.1.6.3 to authenticate the submission. If the third-party is not associated to the GUDID account and to the Labeler DUNS submitted in Section 5.1.6.3, the submission will be rejected.</p>

5.1.3 Device Information

The device information in the manufactured product element includes the following: the primary device identifier, brand name, device description, model or version number, catalog number, product classification – including FDA product code and GMDN Preferred Term code, alternative identifiers (Unit of Use, Direct Marking, Secondary device identifiers), base package device count and package configurations. This section includes all device information listed above in the relative order that it should appear.

Note: that some elements can be serialized (repeated) and the order in the XML is not strictly defined. The elements that fit in this category are as follows:

- Identified Entity – includes how the Labeler may identify a medical device – e.g., model or version number and catalog number.
- Specialized Kind – includes product classification codes for a medical device – e.g., FDA Product Code and GMDN Preferred Term Code.
- Equivalent Entity – includes all device identifiers that are of equivalent representation of a medical device – e.g., Unit of Use DI, Direct Marking DI, and Secondary DI.

The order of the elements in the XML is only critical to group them in like elements and in the order presented above – i.e., all **IdentifiedEntity** elements are placed before **SpecializedKind** elements and all **EquivalentEntity** elements are last in the order. Specific instructions are provided in the subsections below.

5.1.3.1 Device Identifier (DI) Information – Primary Device Identifier Number

The Primary Device Identifier is an identifier that is the main (primary) lookup for a medical device product and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest level of a medical device containing a full UDI. The following XML snippet shows the primary device identifier:

```

<subject>
  <manufacturedProduct classCode="M"
    <manufacturedProduct>
      <code code="12345678901234" codeSystem="1.3.160"/>
      <name>Brand Name</name>
      <desc>Device Description</desc>
    </manufacturedProduct>
  </manufacturedProduct>
</subject>

```

5.1.3.1.1 **ManufacturedProduct classCode**

The *manufacturedProduct@classCode* value must be equal to “MANU” to pass schema validation. Any other value in this field may cause the schema validation to fail.

5.1.3.1.2 **Primary Device Identifier Number (manufacturedProduct.code)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code (1..1)</i>		1..1		This is the container element for the Primary Device Identifier.
	<i>code</i>	1..1	Numeric or Alphanumeric <i>e.g., 14-digit number</i>	This is the device identifier for the DI Record.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/code/@code			
	<i>codeSystem</i>	1..1	<i>OID</i> <i>e.g., GS1, HIBCC or ICCBBA</i>	This is the identifier for the issuing agency for the DI.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/code/@codeSystem				
<i>Business Rules</i>	<ul style="list-style-type: none"> • There is only one primary device identifier for a medical device product, i.e., only one <i>manufacturedProduct.code@code</i> shall be provided in the GUDID submission. • The issuing agency of the primary device identifier shall be used for the unit of use, direct marking and package device identifiers. • The primary device identifier issuing agency shall not appear for any secondary DI provided in the <i>equivalentEntity.definingMaterialKind.code@code</i> attribute. • The Primary DI can be changed during the grace period, which is seven¹⁴ calendar days and starts the day after the DI Record is published. Note that the same document <i>setId</i> element should be used with an increase in version number. • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros. • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length, first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value. 			

¹⁴ GUDID Release 1.2.2, deployed on September 17, 2014, temporarily extended the DI record grace period to 30 calendar days to provide flexibility to users managing their DI record submissions in conjunction with the September 24, 2014 compliance date. We want to emphasize that this is a *temporary* change and will be updated in a future release.

5.1.3.2 Device Information – Brand Name

The Proprietary/Trade/Brand name of the medical device provided in device labeling or in the catalog to identify the device. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol. The following XML Snippet includes the brand name element:

```

<subject>
  <manufacturedProduct classCode="M
  <manufacturedProduct>
    <code code="12345678901234" codeSystem="1.3.160"/>
    <name>Brand Name</name>
    <desc>Device Description</desc>
  
```

5.1.3.2.1 ManufacturedProduct.name

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>name.item</i>		1..1		The <i>name.item</i> element is the container element for describing the Brand/Proprietary, Trade name of the medical device product.
		1..1	Alphanumeric <i>e.g., Brand Name</i>	This is the value for the brand name of the medical device.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/name/text()				
<i>Business Rules</i>	The Brand Name should be no more than 80 characters and should not include symbols other than ® or ™.			

5.1.3.3 Device Information – Device Description

The device description provided by the Labeler should provide any additional relevant information about the device that is not already captured as a distinct GUDID data attribute. The following XML Snippet includes the elements and attributes required for the description:

```

<subject>
  <manufacturedProduct classCode="MANU">
  <manufacturedProduct>
    <code code="12345678901234" codeSystem="1.3.160"/>
    <name>Brand Name</name>
    <desc>Device Description</desc>
  
```

5.1.3.3.1 **ManufacturedProduct.desc**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Desc		1..1		This is a container element for the medical device's description.
	value	1..1	Alphanumeric <i>E.g., Device Description</i>	This is the description of the medical device that is provided by the Labeler.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/desc/text()			
Business Rules	The description provided must be less than 2000 characters.			

5.1.3.4 **Device Information –Version or Model**

The version or model number found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler. The following XML Snippet includes the elements and attributes for the version or model number:

```
<asIdentifiedEntity>
  <id root="e0ff9fe5-1814-4436-95af-23745ef9251b" extension="Model A1"/>
  <code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

The following elements will be found in the GUDID HL7 SPL submission:

5.1.3.4.1 Version or Model Number (*asIdentifiedEntity.id*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Id</i>		1..1		This is the container element for the model number.
	<i>root</i>	1..1	UUID	This is a globally unique identifier for the id being provided.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]/../id/@root			
	<i>Extension</i>	1..1	<i>Alphanumeric e.g., Model A1</i>	This is used to indicate any additional identifiers for the <i>ManufacturedProduct</i> .
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]/../id/@extension			
<i>Business Rules</i>	<p>The version or model number is required.</p> <p>The <i>asIdentifiedEntity.id@root</i>, is a globally unique identifier, which is required by the schema; it should be unique to the Model Number that is provided in the extension. Currently we do not use this value in the GUDID – i.e., it does not have any business rules associated with it.</p> <p>Only the <i>id@extension</i> value will be displayed by the GUDID system for the model number or version number.</p> <p>The version or model number can only be 80 characters in length.</p> <p>A device record can only contain one version or model number. If more than one is submitted, the submission will be rejected.</p>			

5.1.3.4.2 Version or Model Number Type (*asIdentifiedEntity.code*)

The code identifies that the data element is providing a Version or Model Number value.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Code</i>		0..1		This is the container element that identifies the <i>identifiedEntity</i> as the version or model number.
	<i>Code</i>	1..1	Alphanumeric <i>C99285</i>	This is the <i>code</i> that indicates the value is a version or model number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]			
	<i>code System</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem				
<i>Business Rules</i>	The version or model number element must be provided, and the code value must be provided and have a value of "C99285" for the version or model number.			

5.1.3.5 Device Information – Catalog Number

The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product should be included in the DI Record if applicable. Catalog Number is critical for UDI adoption in electronic health records. Please provide catalog number as part of your device record. The following XML Snippet includes the elements and attributes for the catalog number:

```
<asIdentifiedEntity>
  <id root="2zgb4a95-dba1-f5a7-1584-1740n3aa7s8i" extension="CatalogNumber1234"/>
  <code code="C99286" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

The following elements will be found in the GUDID HL7 SPL submission:

5.1.3.5.1 **Catalog Number (*asIdentifiedEntity.id*)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Id</i>		0..1		This is the container element for the model number.
	<i>root</i>	1..1	UUID	This is a globally unique identifier for the id being provided.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99286"]/../id/@root			
	<i>Extension</i>	1..1	<i>Alphanumeric</i> <i>e.g.,</i> <i>CatalogNumber1234</i>	This is used to indicate any additional identifiers for the <i>ManufacturedProduct</i> .
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99286"]/../id/@extension				
<i>Business Rules</i>	<p>The Catalog Number is not required. However, Catalog Number is critical for UDI adoption in electronic health records. Please provide catalog number as part of your device record</p> <p>The <i>asIdentifiedEntity.id@root</i>, is a globally unique identifier, which is required by the schema; it should be unique to the Catalog Number that is provided in the extension. Currently we do not use this value in the GUDID – i.e., it does not have any business rules associated with it.</p> <p>Only the <i>id@extension</i> value will be displayed by the GUDID system for the catalog number.</p> <p>The catalog number can only be 80 characters in length.</p> <p>A device record can only contain one catalog number. If more than one is submitted, the submission will be rejected.</p>			

5.1.3.5.2 Catalog Number Type (*asIdentifiedEntity.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Code</i>		0..1		This is the container element that identifies the <i>identifiedEntity</i> as the catalog number.
	<i>Code</i>	1..1	Alphanumeric <i>C99286</i>	This is the <i>code</i> that indicates the value is a catalog number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem				
<i>Business Rules</i>	If the catalog number element is provided, the code value must be provided and have a value of "C99286" for the catalog number. If there is no catalog number, the <i>asIdentifiedEntity</i> element should not be included with this code value.			

5.1.4 Device Status – Product Classification

The medical device product can be classified to certain broad generic categories using the following two classification systems, the FDA Product Code and the GMDN Preferred Term. Both of these code systems will be used in the DI Record for a medical device:

- **FDA Product Code** - Classification for medical devices issued by the FDA as a three letter code. Visit <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051637.htm> for more information. See Section 5.1.4.1 below for additional information on submitting product codes as part of your GUDID DI record submission.

GMDN Preferred Term (PT) –

GMDN is a system of internationally agreed descriptors used to represent common device types for the purposes of grouping or categorization. Each GMDN Preferred Term has 3 components: Preferred Term Code (5-digit number), Preferred Term Name, and Preferred Term Description. A GMDN Preferred Term can be identified by the GMDN PT. The GMDN PT Code is obtained from the GMDN Agency (www.gmdnagency.com).

- **GMDN PT Code** –Unique five-digit code used to assign a GMDN Preferred Term to a GUDID submission. Contact the GMDN Agency (www.gmdnagency.com) to obtain a valid GMDN PT Code. See Section 5.1.4.2 below for additional information.

The following sections provide the details for submitting each of the product classification elements.

5.1.4.1 FDA Product Code

The following XML Snippet includes the elements and attributes required for FDA Product Code:

```
<asSpecializedKind>  
  <generalizedMaterialKind>  
    <code code="LLH" codeSystem="2.16.840.1.113883.3.150"/>  
  </generalizedMaterialKind>  
</asSpecializedKind>
```

5.1.4.1.1 FDA Product Code (asSpecializedKind.generalizedMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
generalizedMaterialKind.code		0..*		This is the container element for the FDA Product Code.
	code	1..1	Alpha <i>e.g., LLH</i>	This will be the code in the code system for the concept sent to describe the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="2.16.840.1.113883.3.150"]/@code			
	codeSystem	1..1	OID <i>2.16.840.1.113883.3.150</i>	This is the codeSystem that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="2.16.840.1.113883.3.150"]				
Business Rules	<p>The DI Record can have zero-to-many FDA Product codes. The FDA Product Code is required for all medical devices except for :</p> <ul style="list-style-type: none"> • Kits • Licensed IVD (indicated by a premarket number beginning with a BL) <p>However, if a FDA Product Code was assigned during the premarket review process, it should be provided even if it meets one of the conditions above.</p> <p>The codes will be used to pull the FDA Product Code name from the controlled vocabulary.</p> <p>If an invalid code is provided, the GUDID submission will be rejected.</p> <p>Note: At this time, there are no additional validations, such as verifying the submitted code(s) were assigned during premarket authorization; however, the intent is that in the future, additional validation will be implemented with internal FDA/CDRH systems. The reporting of the FDA Product Code(s) should be consistent with that designated during FDA premarket authorization process.</p>			

5.1.4.2 GMDN PT Code

The following XML Snippet includes the elements and attributes required for the GMDN Preferred Term Code:

```

<asSpecializedKind>
  <generalizedMaterialKind>
    <code code="00000" codeSystem="2.16.840.1.113883.6.276"/>
  </generalizedMaterialKind>
</asSpecializedKind>

```

5.1.4.2.1 GMDN Preferred Term Code
(asSpecializedKind.generalizedMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
generalizedMaterialKind.code		1..*		This is the container element for the GMDN code.
	code	1..1	Numeric <i>GMDN Code e.g., 00000</i>	This will be the code in the code system for the concept sent to describe the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="2.16.840.1.113883.6.276"]/@code			
	codeSystem	1..1	OID 2.16.840.1.113883.6.276	This is the codeSystem that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="2.16.840.1.113883.6.276"]				
Business Rules	<p>The DI Record must have one or more GMDN Preferred Terms. The GMDN Preferred Term may be provided as a GMDN Code. The following rules apply when submitting a GMDN Code:</p> <ul style="list-style-type: none"> • A valid and active* GMDN Preferred Term must be submitted. <p>The code will be used to pull the GMDN Preferred Term name and definition from the controlled vocabulary.</p> <p>If an invalid (i.e., the code does not exist) or obsolete (i.e., no longer active) GMDN code is provided, the GUDID submission will be rejected.</p> <p>*If you feel a rejected code is active and valid, contact the GMDN Agency. If there is confirmation that the code is valid and active, contact the FDA UDI Help Desk and request further assistance.</p>			

5.1.5 Device Information – Alternate or Additional Identifiers

There are three device identifiers that are considered alternate or additional identifiers for a medical device product. Each of these is considered an equivalent identifier in the SPL XML and are composed of a code that indicates the type of identifier (e.g., unit of use, direct marking or secondary), a code for the actual device identifier and the issuing agency of that device identifier. The alternate or additional identifiers may be any one of the following:

- **Unit of Use Device Identifier** - An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.
- **Direct Marking Device Identifier**– An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.
- **Secondary Device Identifier** - An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.

The *asEquivalentEntity* element can be used for any of the device identifiers list above as they provide an alternate or additional identifier to the primary device identifier that is used by that medical device product in a specific context.

There are three types of Alternative Device identifiers depicted in the subsections below, Unit of Use, Direct Marking and Secondary DI.

5.1.5.1 Unit of Use Device Identifier

The following XML Snippet includes the elements and attributes required for the Unit of Use device identifier:

```
<asEquivalentEntity>
  <code code="C101717" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <definingMaterialKind>
    <code code="12345678901233" codeSystem="1.3.160"/>
  </definingMaterialKind>
</asEquivalentEntity>
```

5.1.5.1.1 Unit of Use Type (*EquivalentEntity.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		The code element is the container element for the type of device identifier.
	<i>code</i>	1..1	Alphanumeric <i>C101717</i>	The <i>code</i> attribute indicates the type of device identifier, specifically for unit of use device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> for the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code/@codeSystem			
<i>Business Rules</i>	The code must be "C101717".			
	The Unit of Use Device Identifier is required if the device count is greater than one.			

5.1.5.1.2 Unit of Use Device Identifier (*EquivalentEntity.definingMaterialKind.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		The code element is the container element for the unit of use device identifier. Note: A code is required for each <i>definingMaterialKind</i> present in the XML.
	<i>code</i>	0..1	Alphanumeric <i>e.g., 14-digit number</i>	This is the Unit of Use DI for the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]/.. definingMaterialKind/code/@code			
	<i>codeSystem</i>	1..1	OID <i>e.g., 1.3.160</i>	This is the <i>codeSystem</i> for the issuing agency of the unit of use device identifier.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
				<p>XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]/../definingMaterialKind/code/@codeSystem</p>
<i>Business Rules</i>				<p>The Unit of Use DI shall be from the same issuing agency as the Primary DI, provided in the <i>manufacturedProduct.code@code</i> attribute.</p> <p>Base package Device Count should be greater than 1 in order to provide a Unit of Use DI.</p> <p>The Unit of Use DI value can be changed before or after the grace period, as long as the device count > 1 before the grace period expires.</p> <p>If device count is equal to one (device count =1) and the Unit of Use DI is provided, the SPL Submission will be rejected.</p> <p>The following are the input requirements for the DI based on the issuing agency:</p> <ul style="list-style-type: none"> • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length, first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value.

5.1.5.2 Direct Marking Device Identifier

The following XML Snippet includes the elements and attributes required for the Direct Marking device identifier:

```
<asEquivalentEntity>
  <code code="C101678" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <definingMaterialKind>
    <code code="1111111111111111" codeSystem="1.3.160"/>
  </definingMaterialKind>
</asEquivalentEntity>
```

5.1.5.2.1 Direct Marking Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		The code element is the container element for the type of device identifier.
	<i>code</i>	1..1	Alphanumeric <i>C101678</i>	The <i>code</i> attribute indicates the type of device identifier, specifically for Direct Marking DI.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/definingMaterialKind/code[@code="C101678"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> for the type of device identifier.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101678"]/../definingMaterialKind/code/@codeSystem				
<i>Business Rules</i>	The code should be one of the valid values for device identifier type. The DM DI is not required in a DI Record unless the value is different than the Primary DI number.			

5.1.5.2.2 Direct Marking Device Identifier (EquivalentEntity.definingMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		The code element is the container element for the direct marking device identifier. Note: A code is required for each <i>definingMaterialKind</i> present in the XML.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
	code	1..1	Alphanumeric, e.g., 111111111111111111	This is the Direct Marking DI for medical device.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct /manufacturedProduct/asEquivalentEntity/code[@code="C101678"]/../definingMaterial Kind/code/@code				
	code System	1..1	OID e.g., 1.3.160	This is the codeSystem for the issuing agency of the direct marking DI.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct /manufacturedProduct/asEquivalentEntity/code[@code="C101678"]/../definingMaterial Kind/code/@codeSystem				
Business Rules	<p>Only one Direct Marking Device Identifier shall be provided for each DI Record. If more than one is provided, the submission may be rejected.</p> <p>The Direct Marking Device Identifier shall be from the same issuing agency as the Primary DI, as provided in the manufacturedProduct.code@codeSystem attribute.</p> <p>If the element for direct marking exemption is provided as “true”, a Direct Marking DI should not be provided. If direct marking exemption is provided as “true” and Direct Marking DI is provided, the GUDID HL7 SPL submission will be rejected.</p> <p>If a Direct Marking Device Identifier is provided, the “DM DI Different from Primary DI” checkbox will be displayed for the DI Record. No additional values need to be submitted via SPL.</p> <p>The value can be changed before and after the grace period.</p> <p>The following are the input requirements for the DI based on the issuing agency:</p> <ul style="list-style-type: none"> • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length, first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value. 			

5.1.5.3 Secondary DI Number

The following XML Snippet includes the elements and attributes required for the Secondary device identifier:

```
<asEquivalentEntity>
  <code code="C101724" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <definingMaterialKind>
    <code code="1231234566" codeSystem="2.16.840.1.113883.6.18"/>
  </definingMaterialKind>
</asEquivalentEntity>
```

5.1.5.3.1 Secondary DI Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		The code element is the container element for the type of device identifier.
	<i>Code</i>	1..1	Alphanumeric <i>e.g., C101724</i>	The <i>code</i> attribute indicates the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]			
	<i>code System</i>	1..1	OID <i>e.g., 2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> for the type of device identifier.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code/@codeSystem				
<i>Business Rules</i>	The <i>code@code</i> value must be "C101724".			

5.1.5.3.2 Secondary Device Identifier (EquivalentEntity.definingMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		The code element is the container element for the secondary device identifier. Note: A code is required for each <i>definingMaterialKind</i> present in the XML.
	<i>Code</i>	1..1	Alphanumeric <i>e.g., 1231234566</i>	This is the secondary device identifier for the medical device.
<p>XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]/../definingMaterialKind/code/@code</p>				
	<i>code System</i>	1..1	OID <i>e.g.,</i> 2.16.840.1.113883. 6.40	This is the <i>codeSystem</i> for the issuing agency of the secondary device identifier.
<p>XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]/../definingMaterialKind/code/@codeSystem</p>				

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Business Rules</i>				<p>The Secondary DI provided cannot be from the same issuing agency as the Primary DI provided in the <i>manufacturedProduct.code@code</i> attribute.</p> <p>Only one Secondary DI value can be added for each issuing agency not used for the Primary DI. After the DI record grace period expires, Secondary DI values cannot be edited, however, additional Secondary DIs may be added.</p> <p>The following are the input requirements for the DI based on the issuing agency:</p> <ul style="list-style-type: none"> • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length , first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value. • The system shall ensure that a Secondary Device Identifier with NDC issuing agency is 10 or 11 digits in 3 segments with 2 hyphens. Valid formats for 10-digit values are XXXX-XXXX-XX, or XXXXX-XXX-XX, or XXXXX-XXXX-X. The valid format for an 11 digit value is XXXXX-XXXX-XX. • The system shall ensure that a Secondary Device Identifier with NDC issuing agency is a numeric only value.

5.1.5.4 Previous DI Number

Previous Device Identifier is an identifier assigned to a version/model of a medical device prior to the assignment of a new/substitute device identifier to that same version or model, without any changes to the device itself, due to merger and acquisition activity.

The following XML Snippet includes the elements and attributes required for the Previous Device Identifier:

```
<!--asEquivalentEntity>
<code code="C125195" codeSystem="2.16.840.1.113883.3.26.1.1"/>
<definingMaterialKind>
<code code="12345678901234" codeSystem="1.3.160"/>
</definingMaterialKind>
</asEquivalentEntity>
```

5.1.5.4.1 Previous DI Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		The code element is the container element for the type of device identifier.
	<i>Code</i>	1..1	Alphanumeric <i>e.g., C125195</i>	The <i>code</i> attribute indicates the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]			
	<i>code System</i>	1..1	OID <i>e.g., 2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> for the type of device identifier.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code/@codeSystem				
<i>Business Rules</i>	The <i>code@code</i> value must be "C125195".			

5.1.5.4.2 Previous Device Identifier (*EquivalentEntity.definingMaterialKind.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		The code element is the container element for the secondary device identifier. Note: A code is required for each <i>definingMaterialKind</i> present in the XML.
	<i>Code</i>	1..1	Alphanumeric <i>e.g., 1231234566</i>	This is the Previous Device Identifier for the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]/../definingMaterialKind/code/@code			
	<i>code System</i>	1..1	OID <i>e.g., 2.16.840.1.113883.6.40</i>	This is the <i>codeSystem</i> for the issuing agency of the secondary device identifier.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]/../definingMaterialKind/code/@codeSystem				
<i>Business Rules</i>	<p>The Previous DI provided must exist as a valid Primary Device Identifier for another published device record in GUDID.</p> <p>Only one Previous DI value can be added for each device record. Previous DI can be added or edited after the grace period. Previous DI cannot be deleted after the grace period.</p> <p>The following are the input requirements for the DI based on the issuing agency:</p> <ul style="list-style-type: none"> • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length, first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value. 			

5.1.6 Device Characteristics

5.1.6.1 Device Characteristics – Device Count

The Device count is the number of medical devices in the base package (i.e., the base package is the package configuration as labeled with and identified by the DI Record's primary DI number). The following XML Snippet includes the elements and attributes required for the device count:

For example, Base Package = Box of 100 gloves, Primary DI = 101; Device Count = 100

```

<asContent>
  <quantity>
    <numerator value="100"/>
    <denominator/>
  </quantity>
  <containerPackagedProduct>
    <code/>
    <name/>
    <capacityQuantity/>
    <asManufacturedProduct>
    </asManufacturedProduct>
  </containerPackagedProduct>
</asContent>

```

5.1.6.1.1 Device Count Value (quantity.numerator)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Numerator</i>		1..1		This is the container element for the device count
	<i>Value</i>	1..1	Numeric <i>e.g., 100, 1000</i>	This is the device count value of the base package.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/quantity/numerator/@value				
<i>Business Rules</i>	<p>The numerator@value is required. If the value is greater than 1, the Unit of Use Device Identifier is required.</p> <p>If more than one package configuration is provided, the numerator value of each asContent element must be the same.</p> <p>The Denominator element should be provided in your XML file, no value is required.</p>			

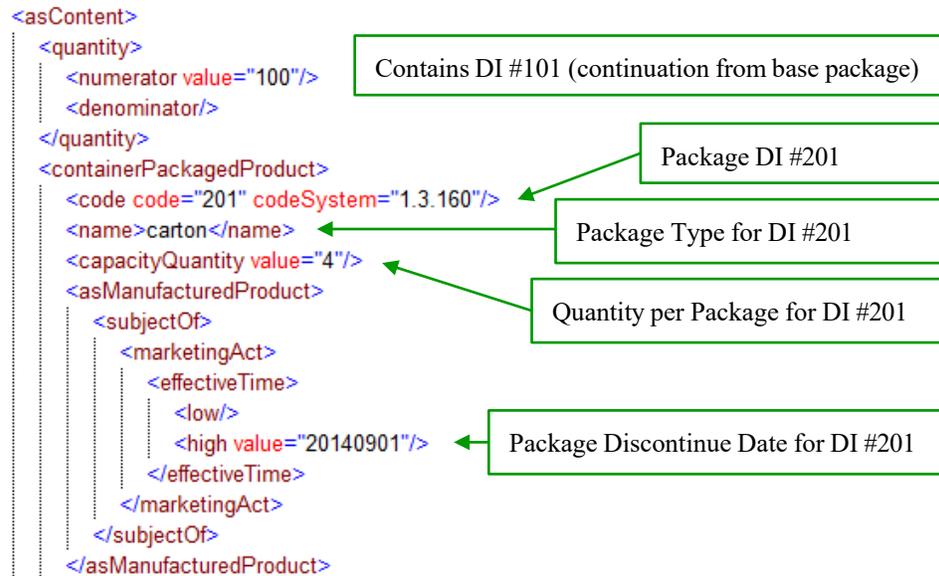
5.1.6.2 **Device Characteristics – Packaging Configuration**

A package configuration is made up of the following elements:

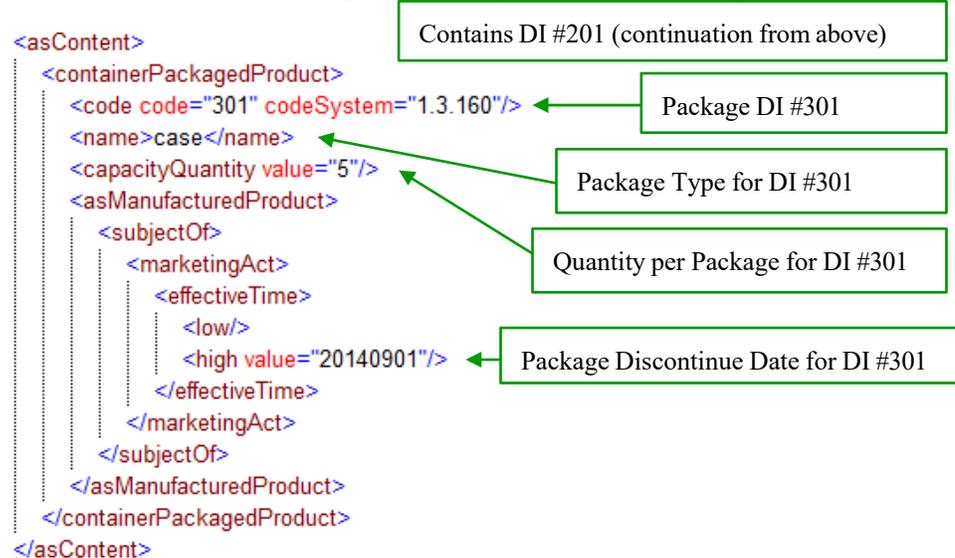
- **Package DI** - A device identifier for the package configuration that contains multiple units of the base package (does not include shipping packages).
 - Examples Package DI (in bold)
 - Base Package DI = 101
 - 4 glove boxes in a Carton -- **Package DI =201** (the DI on the Carton)
 - 5 Cartons in a Case -- **Package DI=301** (the DI on the Case)
- **Package Type** – Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations. The package type can only be 20 characters.
 - Examples of Package Type
 - Carton
 - Case
- **Quantity per Package** – The number of packages with a unique primary DI within a given packaging configuration.
 - Examples of Quantity (in bold)
 - Package DI 201 is a Carton which contains **4** glove boxes.
 - Package DI 301 is a Case which contains **5** Cartons.
- **Package Discontinue Date:** Indicates the date a particular package configuration is discontinued by the labeler.
- **Contains DI Package** - The primary DI for the base package or any lower level package configuration contained within a given package configuration. In the SPL, the Contains DI is the package configuration is nested and takes the value of the higher level package.
 - Examples of Contains DI:
 - Package DI 201 contains base Package DI 101
 - Package DI 301 contains Package DI 201

The following XML Snippet includes the elements and attributes required for the package configuration above:

- 4 glove boxes in a Carton -- **Package DI =201** (the DI on the Carton)



- 5 Cartons in a Case -- **Package DI=301** (the DI on the Case)



5.1.6.2.1 Package DI (containerPackagedProduct.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Code		1..1		This is the container element for the package Device identifier.
	code	1..1	Alphanumeric <i>e.g., 14-digit value</i>	This is the device identifier.
	XPATH: Varies			
	codeSystem	1..1	OID <i>e.g., 1.3.160</i>	This is the codeSystem for the issuing agency of the package device identifier.
	XPATH: Varies			
Business Rules	<p>The issuing agency for Package DI should be the same as the Primary DI.</p> <p>Once the grace period expires, a package configuration cannot be removed from the DI Record. The only change that can be made to a package configuration is changes to the package discontinue date – adding a package discontinue date if null, or updating an existing package discontinue date.</p> <p>The Device Identifier should follow these format requirements:</p> <ul style="list-style-type: none"> • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length, first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value. 			

5.1.6.2.2 Package Type (containerPackagedProduct.name)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
name		0..1		This is the container element for the package type.
		0..1	Alpha <i>e.g., box, case</i>	This is a short package type description.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/name ()			
Business Rules	<p>The value can only be 20 characters in length and is optional.</p> <p>If the package type is provided, it cannot be changed after the grace period.</p>			

5.1.6.2.3 **Quantity per Package (containerPackagedProduct.capacityQuantity)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>capacityQuantity</i>		1..1		This is the container element for the quantity in Package value.
	<i>value</i>	1..1	Numeric <i>e.g., 20, 30</i>	This is the number of products in the package.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/capacityQuantity/@value			
Business Rules	The quantity per package is required if a package configuration is provided. The value needs to be greater than 1 if the Contains DI is the Primary DI (i.e., base package). The quantity per package cannot be changed after the grace period.			

5.1.6.2.4 **Package Discontinue Date**

The package discontinue date consists of two elements as follows.

5.1.6.2.4.1 **Package Discontinue Date (marketingAct.effectiveTime.low)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Low</i>		0..1		This is the container element for the package discontinued date.
	XPATH: /document/component/structuredBody/component/section/subject/asManufacturedProduct/subjectOf/marketingAct/effectiveTime/low/@value			
Business Rules	The date element is required, but no value should be provided.			

Package Discontinue Date (marketingAct.effectiveTime.high)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
High		0..1		This is the container element for the device discontinued date.
	value	1..1	Date Format YYYYMMDD E.g., "20111016"	This is the value for the date the package is discontinued by the labeler.
XPATH: Varies				
Business Rules	<p>The date must follow the format YYYYMMDD.</p> <p>The date is only provided at the time the device product is discontinued by the labeler.</p> <p>The date may be a current date or date in the future. If the date is a date in the past, it cannot be before the DI Record Publish Date. This value can be changed at any time after it has been set.</p> <p>If the DI Record has a Commercial Distribution End Date, the Package Discontinue Date is required; and</p> <ul style="list-style-type: none"> ○ The Package Discontinue Date must be less than or equal to the Commercial Distribution Date (of the base package). ○ The Package Discontinue Date must be less than or equal to the Package Discontinue Date of the packages it contains. <p>The Package DI will still remain in the GUDID system after it reaches the package discontinue date.</p>			

5.1.6.2.5 Contains DI Package (containerPackagedProduct.code or manufacturedProduct.code)

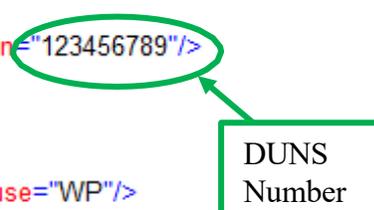
Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Code</i>		1..1		This is the container element for the Contains Device identifier.
	<i>code</i>	1..1	Alphanumeric <i>e.g., 14-digit value</i>	This is the Package DI.
	XPATH: Varies			
	<i>code System</i>	1..1	OID <i>e.g., 1.3.160</i>	This is the OID for the Package DI Issuing Agency.
	XPATH: Varies			
<i>Business Rules</i>	<p>The issuing agency should be the same as the Primary DI's issuing agency.</p> <p>The Contains DI cannot be changed after the grace period.</p> <p>The Device Identifier should follow these format requirements:</p> <ul style="list-style-type: none"> • A device identifier with GS1 as issuing agency shall be greater than 12 digits or equal to 14 digits in length; DIs with 12 or 13 digits should be appended with leading zeros • A device identifier with GS1 issuing agency shall be a numeric only value. • A device identifier with ICCBBA issuing agency shall be 10 or 16 digits in length. • A device identifier with ICCBBA issuing agency shall be an alphanumeric value. • A device identifier with HIBCC issuing agency shall be 6-23 digits in length , first character alphabetic and last character numeric, and cannot include special characters. • A device identifier with HIBCC issuing agency shall be an alphanumeric value. 			

5.1.6.3 Device Information – Company Name – Labeler DUNS Number

The Labeler DUNS Number¹⁵ provided will be used to populate the DI Record with the labeler company name and physical address as shown on the medical device label. To ensure data consistency the company name associated to the Labeler DUNS number should match the company name that appears on the device label. Ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement; however, labelers are encouraged to work towards this model for new products and when making changes to existing products as appropriate.

The following XML Snippet provides the elements and attributes for the Labeler DUNS number:

```
<subjectOf>
  <document>
    <author>
      <assignedEntity>
        <representedOrganization>
          <assignedEntity1>
            <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <representedOrganization>
              <id root="1.3.6.1.4.1.519.1" extension="123456789"/>
            </representedOrganization>
          </assignedEntity1>
          <contactParty>
            <telecom value="tel:+1(999)999-1112" use="WP"/>
            <telecom value="mailto:info@device.com"/>
            <contactPerson/>
          </contactParty>
          <contactParty>
            <telecom value="tel:+1(999)999-1111" use="WP"/>
            <telecom value="mailto:info@device.com"/>
            <contactPerson/>
          </contactParty>
        </representedOrganization>
      </assignedEntity>
    </author>
  </document>
</subjectOf>
```



¹⁵ Note: The Labeler DUNS Number may match the Submitter in Section 5.1.2, but must also be provided for the medical device product in this specified location.

5.1.6.3.1 Type of Organization (assignedEntity1.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Code		1..1		This is the container element for the type of organization.
	code	1..1	Alphanumeric <i>C101684</i>	The code indicates the type of organization, specifically, the Labeler.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101684"]			
	codeSystem	1..1	OID 2.16.840.1.113883.3.26.1.1	This is the codeSystem that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/code/codeSystem				
Business Rules	<p>The code for the organization should always indicate the company as a Labeler and have the code value of C101684 and code system of 2.16.840.1.113883.3.26.1.1.</p> <p>Note: During submitter authentication, the Labeler is compared with the Submitter; and the DUNS Number in this XML location, which is the Device Labeler DUNS Number, will be used to determine if the submitter is authorized to send on behalf of the Labeler. See Section 5.1.2 for detailed business rules for the Submitter.</p>			

5.1.6.3.2

**DUNS Number for Medical Device Product – Labeler DUNS Number
(author.assignedEntity.representedOrganization.assignedEntity1.representedOrganization.id)**

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Id</i>		1..1		This is the container element for the DUNS Number
	<i>root</i>	1..1	OID 1.3.6.1.4.1.519.1	The DUNS number OID is placed in the <i>id@root</i> attribute.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101684"]/../representedOrganization/id/@root			
	<i>extension</i>	1..1	Numeric <i>e.g. 12345689</i>	The Labeler DUNS number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101684"]/../representedOrganization/id/@extension			
<i>Business Rules</i>	<p>The Labeler company name will be pulled from Dun and Bradstreet’s DUNS database based on the Labeler DUNS number provided in this element.</p> <p>The DUNS number can be changed before or after the grace period.</p> <p>Note: the specific Labeler DUNS number needs to be provided to the FDA during the GUDID Account creation process.</p>			

5.1.6.4 Device Contact Information –Customer Contact

The medical device product can be associated to customer contacts. The customer contact will be provided for public use – i.e., this is a consumer or provider contact information for the medical device product.

For each contact, only an email and telephone number shall be provided.

This contact information can be repeated as many times as necessary, i.e., entry of the following four elements are required per contact. The following XML Snippet includes an example of a contact:

```
<subjectOf>
  <document>
    <author>
      <assignedEntity>
        <representedOrganization>
          <assignedEntity1>
            <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <representedOrganization>
              <id root="1.3.6.1.4.1.519.1" extension="123456789"/>
            </representedOrganization>
          </assignedEntity1>
          <contactParty>
            <telecom value="tel:+1(999)999-1112" use="WP"/>
            <telecom value="mailto:info@device.com"/>
            <contactPerson/>
          </contactParty>
          <contactParty>
            <telecom value="tel:+1(999)999-1111" use="WP"/>
            <telecom value="mailto:info@device.com"/>
            <contactPerson/>
          </contactParty>
        </representedOrganization>
      </assignedEntity>
    </author>
  </document>
</subjectOf>
```

5.1.6.4.1 Customer Contact Telephone Number (*contactParty.telecom*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Telecom		1..1		This is the container element for both phone and email.
	value	1..1	Alphanumeric <i>e.g., tel:+1(999)999-9999</i>	The customer contact phone number.
<p>XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/contactParty/code[@code="C101684"]/..//telecom[starts-with(@value, 'tel:')]/@value</p>				
Business Rules	<p>Each ContactParty.ContactPerson element should include two telecom elements. One value should be a phone number and one should be an email. A contact requires a phone number and email address, if a contact is provided.</p> <p>The phone number value should follow the following format, otherwise it may be rejected for invalid format:</p> <ul style="list-style-type: none"> • domestic phone number has no more than 15 digits, formatted as follows: tel:+, country cod, (area code), 3-digit prefix, - 4-digit number; and postd:up to 10-digit extension (optional). <ul style="list-style-type: none"> ○ For example: tel: +1(240)276-0001;postd:12345 • international phone number has no more than 20 digits, formatted as follows: tel:+, phone country, (phone city), phone local, and postd: up to 10-digit extension (optional). <ul style="list-style-type: none"> ○ For example: tel: +011(123)1234567890 or if no phone city, tel:+011()1234567890;postd;12345 <p>The Customer Contact information cannot be duplicated in the DI Record, i.e., each contact must have a unique combination of email and phone number.</p> <p>If you do not have a Customer Contact phone number use the following value:</p> <ul style="list-style-type: none"> ○ For example: tel: +1(999)999-9999 <p>Note: We plan to decouple phone and email fields in a future release.</p> <p>The contact information can be changed during or after the grace period.</p>			

5.1.6.4.2 Customer Contact Email (*contactParty.telecom*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Telecom		1..1		This is the container element for the email address of the contact.
	<i>value</i>	1..1	Alphanumeric <i>e.g., mailto:johndoe@device.com</i>	The email address for the Customer Contact.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/contactParty/code[@code="C101684"]/..../telecom[starts-with(@value, 'mailto:')]/@value			
Business Rules	<p>Each ContactParty.ContactPerson element should include two telecom elements. One value should be a phone number and one should be an email. A contact requires a phone number and email address, if a contact is provided.</p> <p>The email value should follow the following format:</p> <ul style="list-style-type: none"> • mailto:johndoe@device.com <p>Customer Contact information cannot be duplicated in the DI Record, i.e., each contact must have a unique combination of email and phone number.</p> <p>If do not have a Customer Contact email, please enter mailto:xx@xx.xx. We plan to decouple phone and email fields in a future release.</p> <p>The contact information can be changed during or after the grace period</p>			

5.1.6.5 Device Status – Exempt from Premarket Submission

For devices exempt from FDA Premarket regulations or a pre-amendment device, the Labeler should provide the information as shown in the following XML Snippet, which includes the required elements and attributes:

```
<subjectOf>
  <approval>
    <code code="C80438" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </approval>
</subjectOf>
```

5.1.6.5.1 Exempt from Premarket Submission (Approval.code)

The medical device product is exempt from premarket regulations; or is a pre-amendment device.

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		This is the container element for Premarket Authorization Exempt Status.
	<i>code</i>	1..1	Alphanumeric <i>C80438</i>	Code for product exempt from premarket regulations or a pre-amendment device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code="C80438"]/			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code/@codeSystem				
Business Rules	<p>If the product is exempt from premarket regulations or is a pre-amendment device, this element should be provided only once.</p> <p>If the product is exempt from premarket regulations or is a pre-amendment device, it cannot have any premarket submission numbers. If both code values are present, the GUDID submission will be rejected.</p>			

5.1.6.6 Device Status – Premarket Submission – FDA Premarket Submission Number

A premarket submission number can be made up of one or two parts, as follows:

- **Premarket Submission Number** - Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA and NDA.
- **Supplement Number** - Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, BLA, HDE, or PDP.

The following XML Snippet includes the elements and attributes required for premarket submission numbers:

```
<subjectOf>
  <approval>
    <id root="2.16.840.1.113883.3.150" extension="Kxyyyy"/>
    <code code="C80442" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <component typeCode="COMP">
      <approval>
        <!--Supplement #-->
        <id root="2.16.840.1.113883.3.150" extension="000"/>
        <code code="C70862" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </approval>
    </component>
  </approval>
</subjectOf>
```

5.1.6.6.1 FDA Premarket Submission Number (Approval.id)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		0..*		This is the container element for the FDA Premarket Submission number.
	<i>extension</i>	1..1	Alphanumeric <i>e.g. Kxyyyy</i>	This is the premarket submission number issued by the FDA.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/..id/@extension			
	<i>root</i>	1..1	OID <i>2.16.840.1.113883. 3.150</i>	The OID for the FDA Tracking system.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/..id/@root			
<i>Business Rules</i>	<p>The FDA Premarket submission number should be a 6, 7 or 8-character value. The value should include the one or two-letter alpha to indicate the type of authorization, e.g., Premarket Approval = “P” or “BP” and Premarket Notification = “K” or “BK”.</p> <ul style="list-style-type: none"> • CDRH Premarket Submission Numbers must be 7-characters, including 1-alpha and 6 digits; or for DEN premarket number, 3-alpha and 6-digits • CBER Premarket Submission Numbers must be 8-characters, including 2-alpha and 6 digits. • NDA Premarket Submission Numbers may be 6 or 7-characters, including 1-alpha and 5 or 6 digits. <p>Premarket submission numbers will be validated to ensure that the number exists in FDA databases and the product is approved.</p> <p>Additional validations may be included in future, such as verifying that the FDA Product Code and the Listing Number provided in the DI Record match and is consistent with the information provided during premarket approval.</p> <p>The DI Record should include all applicable Premarket Submission numbers.</p> <p>If a premarket submission number is provided, the GUDID submission should not also include an approval element that indicates the product as exempt from premarket regulations or is a pre-amendment device (code = C80438). If both are provided, the GUDID submission will be rejected.</p>			

5.1.6.6.2 Type of FDA Premarket Submission (Approval.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Code		1..1		This is the container element for the type of premarket submission.
	code	1..1	Alphanumeric <i>E.g.</i> <i>C80441</i>	The code for type of premarket approval granted by the FDA.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/			
	codeSystem	1..1	OID <i>2.16.840.1.113883.</i> <i>3.26.1.1</i>	This is the codeSystem that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code/@codeSystem			
Business Rules	The code must be a valid code for a premarket submission; otherwise the GUDID submission will be rejected.			

5.1.6.6.3 Schema Element – component.typeCode

The **component@typeCode** value must be equal to “COMP” to pass schema validation. Any other value in this field may cause the schema validation to fail.

5.1.6.6.4 FDA Premarket Submission Supplement Number (Approval.id)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		1..1		Container element for Premarket Submission Supplement number.
	<i>extension</i>	1..1	Numeric <i>e.g., 001 or 1001</i>	The Premarket Submission Supplement number issued by the FDA.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/../component/approval/code[@code="C70862"]/../id/@extension			
	<i>root</i>	1..1	OID <i>2.16.840.1.113883. 3.150</i>	The OID for the FDA Tracking system.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/../component/approval/code[@code="C70862"]/../id/@root				
<i>Business Rules</i>	<p>The Premarket Submission Supplement Number may include up to a 3 or 4-digit value.</p> <ul style="list-style-type: none"> • CDRH Supplement Numbers are 1, 2, or 3-digits* • CBER Supplement Numbers are 1, 2, 3, or 4-digits** <p>* Note: If a value is sent with less than 3-digits for CDRH supplement numbers, the value will have leading zeroes appended to make it a 3-digit value.</p> <p>** Note: The value will appear as it is submitted for CBER supplement numbers, i.e., no leading zeroes are added.</p> <p>If the Premarket Submission Supplement Number is not provided, the system automatically defaults the value to zero (e.g., 000 (CDRH) or 0 (CBER))</p>			

5.1.6.6.5 FDA Premarket Submission Supplement Type (Approval.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the type of Premarket Authorization Number.
	<i>code</i>	1..1	Alphanumeric <i>C70862</i>	The <i>code</i> value for type of approval granted by the FDA, in this case it is a Premarket Submission Supplement.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/./component/approval/code[@code="C70862"]/			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code!="C101677"]/./component/approval/code/@codeSystem			
Business Rules	The <i>code</i> value must be C70862 for this element. Any invalid codes will cause the GUDID submission to be rejected.			

5.1.6.7 Device Status – FDA Listing Number

Listing number is assigned by the FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f). There may be more than one FDA Listing number for the DI Record being submitted. Medical devices that are HCT/P products with a BL premarket number may not have listing numbers. The following XML Snippet includes the elements and attributes required for the FDA Listing number:

```

<subjectOf>
  <approval>
    <id root="2.16.840.1.113883.3.150" extension="X123456"/>
    <code code="C101677" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </approval>
</subjectOf>

```

5.1.6.7.1 FDA Listing Number (Approval.id)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>id</i>		0..*		This is the container element for the FDA Listing Number.
	<i>root</i>	1..1	OID 2.16.840.1.113883. 3.150	This is a globally unique value for the identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code="C101677"]/..id/@extension			
	<i>extension</i>	1..1	Alphanumeric e.g., X123456	The Listing number issued by the FDA.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code="C101677"]/..id/@root				
<i>Business Rules</i>	<p>The FDA Listing Number should be a 7-character value.</p> <p>The product may have more than one FDA Listing Number, but is not always required. Submit all applicable Listing Numbers for the product.</p> <p>Listing Numbers are required for all medical devices except: HCT/P, Kits and Licensed IVDs.</p> <p>If an invalid or inactive FDA Listing Number is provided upon initial submission, the GUDID submission will be rejected.</p> <p>Existing device records with invalid listing number may be updated as follows –</p> <ul style="list-style-type: none"> • Update the record with an additional valid and active listing number. This will allow the record to be edited with all current business rules. The existing invalid listing number will be retained, and therefore must be submitted as part of you edit file. • If a valid and active listing number is not available, the record may be updated to edit Commercial Distribution End Date and Package Discontinue Date. All other fields cannot be edited. <p>In the future, additional validations against FDA Product Code and Premarket Submission number may be included.</p>			

5.1.6.7.2 FDA Listing Type (Approval.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..*		This is the container element for the FDA Listing type.
	<i>code</i>	1..1	Alphanumeric <i>C101677</i>	The <i>code</i> is the FDA Listing Number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code[@code="C101677"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/approval/code/@codeSystem			
Business Rules	The <i>code@code</i> value must be "C101677"			

5.1.6.8 Device Status and Dates – Commercial Distribution End Date

The Commercial Distribution End Date indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace. The following XML Snippet includes the elements and attributes required for Commercial Distribution End Date:

```

<subjectOf>
  <marketingAct>
    <effectiveTime>
      <low/>
      <high value="20140901"/>
    </effectiveTime>
  </marketingAct>
</subjectOf>

```

5.1.6.8.1 Commercial Distribution End Date (marketingAct.effectiveTime.low)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Low		1..1		This is the container element for the Commercial Distribution End Date.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/marketingAct/effectiveTime/low/@value				
Business Rules	The date element tag is required, but no value should ever be provided.			

5.1.6.8.2 Commercial Distribution End Date (marketingAct.effectiveTime.high)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
High		1..1		This is the container element for Commercial Distribution End Date
	value	1..1	Date Format YYYYMMDD E.g., "20111016"	This is the date value for the date the device product is no longer in commercial distribution.
Business Rules	<p>The date must follow the format YYYYMMDD.</p> <p>The date is only provided at the time the device product is no longer actively marketed.</p> <p>The DI Record will still remain in the GUDID system.</p>			
XPATH	/document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/marketingAct/effectiveTime/high/@value			

5.1.6.9 Device Information – Device Subject to Direct Marking, but Exempt

The Labeler can claim their device is subject to Direct Marking under 21 CFR 801.45, but exempt. The following XML Snippet includes the element that indicates the exemption:

```

<subjectOf>
  <characteristic>
    <code code="C101679" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>

```

5.1.6.9.1 Device Subject to Direct Marking (DM), but Exempt (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		The code element is the container element for Device Subject to Direct Marking (DM), but Exempt.
	<i>code</i>	1..1	Alphanumeric <i>C101679</i>	The <i>code</i> for Device Subject to Direct Marking (DM), but Exempt.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101679"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	<p>If the Device is subject to Direct Marking, but exempt, the <i>code@code</i> value must be “C101679”.</p> <p>If this data element does not apply to the DI Record, a characteristic data element does not need to be provided.</p>			

5.1.6.9.2 Device Subject to Direct Marking (DM), but Exempt Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the direct marking exemption indicator.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type			
	<i>Value</i>	1..1	Alpha “true” or “false”	This is the <i>value</i> attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101679"]/..value/@value			
<i>Business Rules</i>	<p>Any value other than “true or “false” will fail schema validation.</p> <ul style="list-style-type: none"> • If the value is set to “true”, a Direct Marking DI will not be allowed. • If the value is set to “false”, a Direct Marking DI value is required only if the value is different than the Primary DI. • If the data element value is not provided, “false” will be stored in the database. <p>The value can be submitted as part of the initial submission, or changed after the grace period, but the rules above will always apply.</p> <p>Note: when reading the error messages the system will convert true = “Y” and false=“N”</p>			

5.1.6.10 Device Characteristics – Clinically Relevant Size

The clinically relevant size measurement for the medical device is captured under device characteristics. The following XML Snippet includes the elements and attributes required clinically relevant size:

```

<subjectOf>
  <characteristic>
    <code code="C96684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="PQ" value="200" unit="cm"/>
  </characteristic>
</subjectOf>

```

5.1.6.10.1 Clinically Relevant Size Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>				
	<i>code</i>	1..1	Alphanumeric <i>e.g., C96684</i>	The <i>code</i> to indicate clinically relevant size type, the dimension type for the clinically relevant measurement of the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list – codes vary by type"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem				
<i>Business Rules</i>	The <i>code@code</i> value needs to be one of the valid values for clinically relevant size. The code value will determine the valid units of measure for the size type. See controlled vocabulary documentation for details.			

5.1.6.10.2 Clinically Relevant Size Value and Unit of Measure (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the clinically relevant size quantity.
	<i>xsi:type</i>	1..1	Physical Quantity <i>PQ</i>	The <i>xsi:type</i> indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../../value/@xsi:type			
	<i>value</i>	1..1	Alpha Numeric <i>e.g., 3</i>	This is the numeric <i>value</i> for the clinically relevant size measurement of the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../../value/@value			
	<i>unit</i>	1..1	Alpha Numeric <i>e.g., cm, [in_i], U/L</i>	This is the value of the <i>unit</i> of measure associated with each clinically relevant size.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../../value/@unit				
Business Rules	<p>If the clinically relevant size code is a structured measure, the value and unit must be provided.</p> <p>The unit of measure submitted must be allowed for the given size type – e.g., the size type outer diameter (C96684) must have a unit of measure for a valid length size. See controlled vocabulary documentation for details.</p>			

5.1.6.11 Device Characteristics – Clinically Relevant Size – Device Size Text

Clinically relevant device size text field can be used to provide additional undefined device size not represented in the GUDID’s clinically relevant size list. The following XML Snippet includes the elements and attributes required for providing a free-text description of the clinically relevant size:

```

<subjectOf>
  <characteristic>
    <code code="C106041" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="ST">Add size Text</value>
  </characteristic>
</subjectOf>

```

5.1.6.11.1 Clinically Relevant Size Device Size Text Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for clinically relevant size text.
	<i>code</i>	1..1	Alphanumeric <i>C106041</i>	This is the code to indicate the type of characteristic being identified for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	The <i>code@code</i> value must be "C106041".			

5.1.6.11.2 Clinically Relevant Size Text (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the size text.
	<i>xsi:type</i>	1..1	String <i>ST</i>	The <i>xsi:type</i> indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]/..value@xsi:type			
	<i>value</i>	1..1	Alpha Numeric e.g., medium	This is the value attribute for the clinically relevant size text.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]/..value/text()			
Business Rules	The text element can only be used when the code is "C106041" is provided. If the characteristic element has any other code value with a string value, the GUDID submission will be rejected.			

5.1.6.12 Device Characteristics – Storage and Handling Requirements

Storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure are provided as device characteristics. The following XML Snippet includes the elements and attributes required for these requirements:

```
<subjectOf>
  <characteristic>
    <code code="C101707" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="IVL_PQ">
      <low value="-40" unit="C"/>
      <high value="158" unit="C"/>
    </value>
  </characteristic>
</subjectOf>
```

5.1.6.12.1 Storage and Handling Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..*		This is the container element for the storage and handling type.
	<i>code</i>	1..1	Alphanumeric <i>e.g., C101707</i>	This is the code to indicate the storage and handling type being identified for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
<i>Business Rules</i>	The code should be one of the valid values.			
	If a storage and handling element is sent, the <i>code@code</i> and <i>code@codeSystem</i> is required.			

5.1.6.12.2 Storage and Handling Value and Unit of Measure (*characteristic.value.low*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value@xsi:type</i>	<i>xsi:type</i>	1..1	String <i>IVL_PQ</i>	The <i>xsi:type</i> indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/..value/@xsi:type			
<i>value.low</i>		1..1		This is the container element for the storage and handling value.
	<i>value</i>	1..1	Numeric <i>e.g., 10, 20</i>	The value of the storage or handling value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/..value/low/@value			
	<i>unit</i>	1..1	Alpha Numeric <i>e.g., Celsius</i>	This is the unit of measure for the storage or handling unit.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/..value/low/@unit			
<i>Business Rules</i>	<p>If a storage or handling requirement is provided – either the low or high value is required. The unit must also be provided. If the low and high value is provided, the unit of measure must be the same.</p> <p>The following rules can be applied to indicate the low value for storage or handling conditions:</p> <ul style="list-style-type: none"> • provide when the storage and handling condition has a range, this is the lower end of that range (and the upper end of the range should be provided as the high value). • provide when the storage and handling condition value is greater than this value (no value will be provided in the high value). • provide when the storage and handling condition is exactly equal to a value (note-same value will be entered in high@value) 			

5.1.6.12.3 Storage and Handling Value and Unit of Measure (*characteristic.value.high*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value@xsi:type</i>	<i>xsi:type</i>	1..1	String <i>IVL_PQ</i>	The <i>xsi:type</i> indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/..value/@xsi:type			
<i>value.high</i>		1..1		This is the container element for the storage and handling condition.
	<i>value</i>	1..1	Numeric <i>e.g., 10, 20</i>	The value of the storage or handling condition.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/..value/high/@value			
	<i>unit</i>	1..1	Alpha Numeric <i>e.g., Celsius</i>	This is the unit of measure for the storage or handling condition.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/..value/high/@unit			
<i>Business Rules</i>	<p>If a storage or handling requirement is provided – either the low or high value is required. The unit must also be provided. If the low and high value is provided, the unit of measure must be the same.</p> <p>The following rules can be applied to indicate the high value for storage or handling conditions:</p> <ul style="list-style-type: none"> • provide when the storage and handling condition has a range, this is the upper end of that range (and the lower end of the range should be provided as the low value). • provide when the storage and handling condition value is less than this value (no value will be provided in the low value). • provide when the storage and handling condition is exactly equal to a value (note- same value will be entered in low@value) 			

5.1.6.13 Device Characteristics – Special Storage Conditions

Indicates any special storage requirements for the device where the value is not structured (e.g., free text instructions for storage and handling conditions). The following XML Snippet includes the elements and attributes required for special storage conditions:

```
<subjectOf>
  <characteristic>
    <code code="C101704" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="ST1">Keep out of sunlight</value>
  </characteristic>
</subjectOf>
```

5.1.6.13.1 Special Storage Condition Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Code</i>		0..*		This is the container element for the storage and handling type.
	<i>Code</i>	1..1	Alphanumeric <i>C101704</i>	Code to indicate special storage and handling conditions for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
<i>Business Rules</i>	If there is a special storage requirement, the <i>code@code</i> value must be "C101704". If a special storage requirement does not exist, a characteristic element with this code should not be provided.			

5.1.6.13.2 Special Storage Condition Text (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Value</i>		1..1		This is the container element for the special storage text.
	<i>xsi:type</i>	1..1	String <i>ST</i>	The <i>xsi:type</i> indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]/../value/@xsi:type			
	<i>Value</i>	1..1	Alphanumeric e.g., “keep out of sunlight”	This is the value attribute for special storage condition.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]/../value/text()				
<i>Business Rules</i>	<p>The <i>xsi:type</i> value must be “ST”.</p> <p>The text element can only be used when the code is “C101704” is provided.</p> <p>If the characteristic element has any other code value with a string value, the GUDID submission will be rejected.</p>			

5.1.6.14 Device Characteristics – Packaged as Sterile

The Packaged as Sterile indicator is to designate the medical device is free from viable microorganisms (see ISO/TS 11139). The following XML Snippet includes the elements and attributes required for devices packaged as sterile:

```

<subjectOf>
  <characteristic>
    <code code="C101676" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>

```

5.1.6.14.1 Device Packaged as Sterile Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Code		1..1		This is the container element for the device packaged as sterile indicator.
	Code	1..1	Alphanumeric <i>C101676</i>	This is the code to indicate the type of characteristic being identified for a device product, specifically the Packaged as sterile indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]			
	codeSystem	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the codeSystem that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem				
Business Rules	The message must have a Device packaged as Sterile element and the code@code value must be "C101676".			

5.1.6.14.2 Device Packaged As Sterile Value (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
Value		1..1		This is the container element for the value of Device Packaged as Sterile.
	xsi:type	1..1	Boolean <i>BL</i>	The xsi:type specifies the data type for the Device Packaged as Sterile Indicator value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]/../value/@xsi:type			
	Value	1..1	Alpha "true" or "false"	Value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]/../value/@value				
Business Rules	The xsi:type value must be "BL".			
	The value must be "true" or "false. If any other value is provided, the GUDID submission will be rejected.			

5.1.6.15 Device Characteristics – Sterilization Method

If the medical device should be sterilized prior to use, the sterilization method should be provided for the medical device. The following XML Snippet includes the elements and attributes required for the sterilization method:

```
<subjectOf>
  <characteristic>
    <code code="C84382" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="CD" code="C101697" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </characteristic>
</subjectOf>
```

5.1.6.15.1 Sterilization Method Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Code</i>		0..*		This is the container element for the sterilization method.
	<i>Code</i>	1..1	Alphanumeric <i>C84382</i>	The <i>code</i> attribute indicates the sterilization method for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/s subjectOf/characteristic/code[@code="C84382"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/s subjectOf/characteristic/code/codeSystem			
<i>Business Rules</i>	If the medical device requires sterilization prior to use, the Sterilization Method must be in the message and the <i>code@code</i> value must be “C84382”.			
	If the sterilization method is provided, the system will also indicate that the device “Requires Sterilization Prior to Use”.			
	If the device does NOT require sterilization prior to use, then this characteristic element does not need to be provided in the xml.			

5.1.6.15.2 Sterilization Method Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>Value</i>		1..1		This is the container element for the Sterilization Method Value
	<i>xsi:type</i>	[1..1]	Alphanumeric <i>CD</i>	The <i>xsi:type</i> specifies the data type for the sterilization method.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101712"]/../value/@xsi:type			
	<i>value</i>	[1..1]	Alphanumeric e.g., C101712	This is the <i>value</i> attribute for sterilization method.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C84382"]/../value/@code			
<i>Business Rules</i>	The <i>xsi:type</i> value must be “CD”			
	A valid <i>value</i> must be provided from the sterilization method codes.			

5.1.6.16 Device Characteristics – Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)

This attribute is used to indicate that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. The following XML Snippet includes the elements and attributes required for this indicator:

```

<subjectOf>
  <characteristic>
    <code code="C101673" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>

```

5.1.6.16.1 Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437) Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the ‘Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)’ indicator.
	<i>code</i>	1..1	Alphanumeric <i>C101673</i>	Code value to indicate if the ‘Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)’.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	The Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437) element is required and the <i>code@code</i> value must be “C101673”			

5.1.6.16.2 Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437) Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437) indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]/../value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]/../value/@value				
<i>Business Rules</i>	<p>The <i>xsi:type</i> value must be "BL".</p> <p>The <i>value</i> must be "true" or "false". If any other value is provided, the GUDID submission will be rejected.</p> <p>If this value is "true", the Device labeled as "Not made with natural rubber latex" cannot also be true. Also see rules for Device labeled as "Not made with natural rubber latex".</p>			

5.1.6.17 Device Characteristics – Device labeled as "Not made with natural rubber latex"

This attribute is used to indicate that natural rubber latex was not used as materials in the manufacture of the medical product and container. This attribute is only applicable to devices not subject to the requirements under 21 CFR 801.437. The following XML Snippet includes the elements and attributes required for this indicator:

```

<subjectOf>
  <characteristic>
    <code code="C106038" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>

```

5.1.6.17.1 Device labeled as "Not made with natural rubber latex" (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		Container element for the 'Device labeled as "Not made with natural rubber latex"' indicator.
	<i>code</i>	1..1	Alphanumeric <i>C106038</i>	The <i>code</i> attribute to indicate the 'Device labeled as "Not made with natural rubber latex"' indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
<i>Business Rules</i>	<p>The element "Not made with natural rubber latex" is not required. If it is provided, the <i>code@code</i> value must be "C106038".</p> <p>If this data element does not apply to the DI Record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it "false" in the database.</p> <p>If the element is provided, see business rules for the value element.</p>			

5.1.6.17.2 Device labeled as "Not made with natural rubber latex" Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		Container element for the value of Device labeled as "Not made with natural rubber latex"
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the Device labeled as "Not made with natural rubber latex" indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]/../value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the <i>value</i> attribute for the boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]/../value/@value			
Business Rules	<p>The <i>xsi:type</i> value must be "BL".</p> <p>If the value is false, the element should be excluded. However, if it is included, the <i>value</i> must be "true" or "false. If any other value is provided, the GUDID submission will be rejected.</p> <p>If Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437) is "true", then the Device labeled as 'Not made with natural rubber latex' value cannot also be true. Also see section for Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)</p>			

5.1.6.18 Device Characteristics – For Single Use

The Single Use indicator is to designate that the device is intended for one use or on a single patient during a single procedure. The following XML Snippet includes the elements and attributes required for single use products:

```

<subjectOf>
  <characteristic>
    <code code="C53602" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>

```

5.1.6.18.1 For Single Use Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the single use indicator.
	<i>code</i>	1..1	Alphanumeric <i>C53602</i>	This is the <i>code</i> attribute to indicate the type of characteristic being identified for a device product, specifically the single use indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]			
	<i>codeSystem</i>	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	The Single-use element is required and the <i>code@code</i> value must be "C53602"			

5.1.6.18.2 For Single Use Value (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of the single use indicator.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the Single Use indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]/..value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]/..value/@value			
Business Rules	The <i>xsi:type</i> value must be "BL".			
	The <i>value</i> must be "true" or "false". If any other value is provided, the GUDID submission will be rejected.			

5.1.6.19 Device Characteristics – Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)

This attribute indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3. The following XML Snippet includes the elements and attributes required:

```
<subjectOf>
  <characteristic>
    <code code="C101674" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

5.1.6.19.1 Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		Container element for the ‘Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)’ indicator.
	<i>code</i>	1..1	Alphanumeric <i>C101674</i>	This is the code to indicate the type of characteristic being identified for a device product, specifically the ‘Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)’ indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101674"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
<i>Business Rules</i>	The <i>code@code</i> value must be “C101674” if the medical device is an HCT/P product. If the <i>characteristic</i> element is provided, it must have a value element. If this data element does not apply to the DI Record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it “false” in the database.			

5.1.6.19.2 Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		Container element for the Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) indicator value.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101674"]/../value/@xsi:type			
	<i>Value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101674"]/../value/@value				
<i>Business Rules</i>	The <i>xsi:type</i> value must be "BL".			
	The <i>value</i> must be "true" or "false. If any other value is provided, the GUDID submission will be rejected.			

5.1.6.20 Device Characteristics – Kit

This attribute is used to indicate that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices that are packaged together to achieve a common intended use and is being distributed as a medical device. The following XML Snippet includes the elements and attributes required:

```

<subjectOf>
  <characteristic>
    <code code="C50021" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>

```

5.1.6.20.1 Kit Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		This is the container element for the Kit indicator.
	<i>Code</i>	1..1	Alphanumeric <i>C50021</i>	Code to indicate the type of characteristic being identified for a device product, specifically the kit indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem				
<i>Business Rules</i>	The Kit element is not required. If the medical device is a kit, the <i>code@code</i> value must be “C50021” If this data element does not apply to the DI Record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it “false” in the database.			

5.1.6.20.2 Kit Value (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the kit indicator value.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the kit indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]/../value/@xsi:type			
	<i>value</i>	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]/../value/@value				
<i>Business Rules</i>	The <i>xsi:type</i> value must be “BL”. The <i>value</i> must be “true” or “false. If any other value is provided, the GUDID submission will be rejected.			

5.1.6.21 Device Characteristics – Combination Product

This attribute is used to indicate if a the medical device product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case. The following XML Snippet includes the elements and attributes required:

```
<subjectOf>
  <characteristic>
    <code code="C54696" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
```

5.1.6.21.1 Combination Product Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		This is the container element for the combination product indicator.
	<i>code</i>	1..1	Alphanumeric <i>C54696</i>	The <i>code</i> indicates the type of characteristic being identified for a device product, specifically the combination product indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/s subjectOf/characteristic/code[@code="C54696"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/s subjectOf/characteristic/code/@codeSystem				
Business Rules	The Combination Product element is not required. If the medical device is a Combination Product, the <i>code@code</i> value must be “C54696”			
If this data element does not apply to the DI Record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it “false” in the database.				

5.1.6.21.2 Combination Product Value (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the combination product indicator.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the combination product indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C54696"]/..value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C54696"]/..value/@value			
Business Rules	The <i>xsi:type</i> value must be "BL".			
	The <i>value</i> must be "true" or "false. If any other value is provided, the GUDID submission will be rejected.			

5.1.6.22 Device Characteristics – Production Identifier in UDI

In GUDID, the production identifiers appear as a Boolean value to indicate if the production identifier appears on the Label as a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device, unless excepted:

- the lot or batch number within which a device was manufactured;
- the serial number of a specific device;
- the expiration date of a specific device;
- the date a specific device was manufactured;
- and, for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c) (Note: The data element in GUDID is "Donation Identification Number).

5.1.6.22.1 Production Identifier - Lot or Batch Number

The following XML Snippet includes the elements and attributes required for products labeled with a lot or batch number:

```

<subjectOf>
  <characteristic>
    <code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>

```

5162211

Lot or Batch Number Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the lot or batch number indicator.
	<i>code</i>	1..1	Alphanumeric <i>C101672</i>	This is the code to indicate the type of characteristic being identified for a device product, specifically the lot or batch number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	The Lot or Batch Number is required and the <i>code@code</i> value must be “C101672”.			

5162212

Lot or Batch Number Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of lot or batch number.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the lot or batch number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]/../value/@xsi:type			
	<i>value</i>	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]/../value/@value			
Business Rules	The <i>xsi:type</i> value must be “BL”.			
	The <i>value</i> must be “true” or “false”. If any other value is provided, the GUDID submission will be rejected.			

5.1.6.22.2 Production Identifier – Serial Number

The following XML Snippet includes the elements and attributes required for products labeled with a serial number:

```

<subjectOf>
  <characteristic>
    <code code="C101671" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>

```

5.1.6.22.2.1 Serial Number Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the serial number indicator.
	<i>code</i>	1..1	Alphanumeric <i>C101671</i>	This is the <i>code</i> to indicate the type of characteristic being identified for a device product, specifically the serial number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	The Serial Number element is required and the <i>code@code</i> value must be "C101671"			

Serial Number Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
value		1..1		This is the container element for the value of serial number.
	xsi:type	1..1	Boolean <i>BL</i>	The xsi:type specifies the data type for the serial number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]/../value/@xsi:type			
	value	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]/../value/@value				
Business Rules	The xsi:type value must be "BL".			
				The value must be "true" or "false". If any other value is provided, the GUDID submission will be rejected.

5.1.6.22.3 Production Identifier - Manufacturing Date

The following XML Snippet includes the elements and attributes required for products labeled with manufacturing date:

```

<subjectOf>
  <characteristic>
    <code code="C101669" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>

```

5.162231

Manufacturing Date Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the manufacture date indicator.
	<i>code</i>	1..1	Alphanumeric <i>C101669</i>	This is the <i>code</i> to indicate the type of characteristic being identified for a device product, the manufacture date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem				
Business Rules	The Manufacturing Date is required and the <i>code@code</i> value must be "C101669"			

5.162232

Manufacturing Date Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of the manufacturing date indicator.
	<i>xsi:type</i>	1..1	Boolean <i>e.g., BL</i>	The <i>xsi:type</i> specifies the data type for the manufacturing date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]/../value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]/../value/@value				
Business Rules	The <i>xsi:type</i> value must be "BL".			
	The <i>value</i> must be "true" or "false". If any other value is provided, the GUDID submission will be rejected.			

5.1.6.22.4 Production Identifier – Expiration Date

The following XML Snippet includes the elements and attributes required for products labeled with an expiration date:

```
<subjectOf>
  <characteristic>
    <code code="C101670" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

5.1.6.22.4.1 Expiration Date Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the expiration date indicator.
	<i>code</i>	1..1	Alphanumeric <i>C101670</i>	This is the code to indicate the type of characteristic being identified for a device product, specifically the expiration date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem				
Business Rules	The Expiration Date element is required and the <i>code@code</i> value must be "C101670"			

Expiration Date Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
value		1..1		This is the container element for the value of the expiration date indicator.
	xsi:type	1..1	Boolean <i>BL</i>	The xsi:type specifies the data type for the manufacture date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]/../value/@xsi:type			
	value	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]/../value/@value				
Business Rules	The xsi:type value must be "BL".			
The value must be "true" or "false". If any other value is provided, the GUDID submission will be rejected.				

5.1.6.22.1 Production Identifier – Donation Identification Number

The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation. It can be found on the device label or packaging. The following XML Snippet includes the elements and attributes required for products labeled with a donation identification number:

```

<subjectOf>
  <characteristic>
    <code code="C113843" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>

```

5.16221.1

Donation Identification Number Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the donation identification number indicator.
	<i>code</i>	1..1	Alphanumeric <i>C113843</i>	This is the code to indicate the type of characteristic being identified for a device product, specifically the donation identification number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883. 3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
Business Rules	The Donation Identification Number is required and the <i>code@code</i> value must be “C113843”.			

5.16221.2

Donation Identification Number Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of donation identification number.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the donation identification number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]/../value/@xsi:type			
	<i>value</i>	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]/../value/@value			
Business Rules	The <i>xsi:type</i> value must be “BL”.			
	The <i>value</i> is required and must be “true” or “false. If any other value is provided, the GUDID submission will be rejected.			

5.1.6.23 Device Characteristics – MRI Safety Status

This attribute is used to indicate the MR safety status of the device (see ASTM F2503-13 standard). The following XML Snippet includes the elements and attributes required for the MRI Safety Status question, “What MRI safety information does the labeling contain?”:

```
<subjectOf>
  <characteristic>
    <code code="C106044" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="CD" code="C106045" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </characteristic>
</subjectOf>
```

5.1.6.23.1 MRI Safety Status Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		1..1		This is the container element for the sterilization method.
	<i>code</i>	1..1	Alphanumeric <i>C106044</i>	This is the code to indicate the MRI Safety Status of the medical device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/codeSystem			
<i>Business Rules</i>	A response to, “What MRI safety information does the labeling contain?” is required for all DI Records and the <i>code@code</i> value must be “C106044”.			

5.1.6.23.2 MRI Safety Status Value (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the MRI Safety Status.
	<i>xsi:type</i>	[1..1]	Alphanumeric <i>CD</i>	The <i>xsi:type</i> specifies the data type for the MRI Safety Status.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]/../value/@xsi:type			
	<i>value</i>	[1..1]	Alphanumeric e.g., C106044	This is the value attribute for the <i>coded value</i> .
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]/../value/@value			
<i>Business Rules</i>	<p>The <i>xsi:type</i> value must be “CD”</p> <p>A valid <i>value</i> must be provided from the MRI Safety Status, consult the code list for valid values</p> <p>Only one characteristic element with a MRI Safety Status value may be provided.</p> <p>The value provided will be displayed for the following question on the GUDID user interface, “What MRI safety information does the labeling contain?”</p>			

5.1.6.24 Device Characteristics – Prescription Use (*Rx*)

The following XML Snippet includes the elements and attributes for devices that are for prescription use:

```

<subjectOf>
  <characteristic>
    <code code="C28180" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>

```

5.1.6.24.1 Prescription Use (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		This is the container element for the manufacture date indicator.
	<i>code</i>	1..1	Alphanumeric <i>C28180</i>	This is the <i>code</i> to indicate the type of characteristic being identified for a device, prescription use.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C28180"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem				
<i>Business Rules</i>	The Prescription Use element is not required. If it is provided, the <i>code@code</i> value must be "C28180"			
If this data element does not apply to the DI Record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it "false" in the database.				

5.1.6.24.2 Prescription Use Value (*characteristic.value*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of the prescription use indicator.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the prescription use indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C28180"]/..value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C28180"]/..value/@value			
<i>Business Rules</i>	The <i>xsi:type</i> value must be "BL".			
The <i>value</i> must be "true" or "false. If any other value is provided, the GUDID submission will be rejected.				

5.1.6.25 Device Characteristics – Over the Counter (OTC)

The following XML Snippet includes the elements and attributes for devices that do not require a prescription to use and can be purchased over the counter (OTC):

```
<subjectOf>
  <characteristic>
    <code code="C54068" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
```

5.1.6.25.1 Over the Counter Type (*characteristic.code*)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>code</i>		0..1		This is the container element for the manufacture date indicator.
	<i>code</i>	1..1	Alphanumeric <i>C54068</i>	This is the <i>code</i> to indicate the type of characteristic being identified for a device, over the counter.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C54068"]			
	<i>codeSystem</i>	1..1	OID <i>2.16.840.1.113883.3.26.1.1</i>	This is the <i>codeSystem</i> that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem			
<i>Business Rules</i>	The Over the Counter element is not required. If it is provided, the <i>code@code</i> value must be “C54068”.			
	If this data element does not apply to the DI Record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it “false” in the database.			

5.1.6.25.2 Over the Counter Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed <i>Examples</i>	Description <i>Instructions</i>
<i>value</i>		1..1		This is the container element for the value of the over the counter indicator.
	<i>xsi:type</i>	1..1	Boolean <i>BL</i>	The <i>xsi:type</i> specifies the data type for the over the counter indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C54068"]/./value/@xsi:type			
	<i>value</i>	1..1	Alpha "true" or "false"	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C54068"]/./value/@value			
<i>Business Rules</i>	The <i>xsi:type</i> value must be "BL".			
	The <i>value</i> must be "true" or "false. If any other value is provided, the GUDID submission will be rejected.			

6. XML MESSAGE SAMPLE

```
<?xml version="1.0" encoding="UTF-8"?>
```

<!--Note: This GUDID SPL XML Sample is not meant to be valid against the business rules for a GUDID submission. This is a comprehensive example of all the potential elements that can be submitted to the GUDID. Do not attempt to submit this sample as a test submission.-->

```
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 GUDIDSPL.xsd">
```

<!--The document element is administrative information. (all elements are required)-->
<!--id@root is a globally unique identifier for the submission and should be created by the sending system. The sender should be following the algorithm rules set for in OSF's Universally Unique Identifier standards.-->

<!--code@code for the submission type (GUDID Submission = C101716)-->
<!--effectiveTime@value for the DI Record publish date (note that this cannot be a date in the past - i.e., today's date or future date); all dates should be formatted as yyyyymmdd -->

<!--setId@root is a globally unique identifier for the document that will be used to link subsequent versions of the DI Record with previous versions. Note this is also a UUID, and must follow the rules for generating a globally unique identifier value.-->

<!--versionNumber@value is "1" for the initial submission and increments by one for any updates to the DI Record-->

```
<id root="57863671-1527-4e51-b26b-3065a868d949"/>
```

```
<code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

```
<effectiveTime xsi:type="TS" value="20131118"/>
```

```
<setId root="57863671-1527-4e51-b26b-3065a868d948"/>
```

```
<versionNumber value="1"/>
```

<!--The author element provides administrative information about who is submitting the DI Record. One author is required-->

<!--To provide the DUNS number for the Submitter Organization. This information will be used for validation activities only-->

<!--code@code is the coded value for either the Labeler Organization (C101684) or Third-Party (C101710)-->

<!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->

<!--id.root= DUNS OID 1.3.6.1.4.1.519.1; this is the OID for Dun & Bradstreet-->

<!--id.extension = DUNS # for the Labeler Organization (can be the parent or corporate DUNS or the Secondary/Labeler DUNS) or the Third Party submitting the HL7 SPL-->

<!--Note the system will pull the data from Dun & Bradstreet to display the company name and physical address.-->

<!--Only one value is expected for the author. The sample shows both, but the sender should indicate the correct value for who is submitting the XML to the FDA.-->

```
<author>
```

<!--Organization submitting the SPL XML (one and only one required)-->

```
<assignedEntity>
```

```
<representedOrganization>
```

<!--If the submitter-organization is the Secondary Labeler organization DUNS, the code=C101684-->

```
<assignedEntity1>
```

```
<code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

```
<representedOrganization>
```

```
<id root="1.3.6.1.4.1.519.1" extension="123456789"/>
```

```
</representedOrganization>
```

```
</assignedEntity1>
```

```
</representedOrganization>
```

```
</assignedEntity>
```

```
</author>
```

```
<component>
```

```
<structuredBody>
```

```
<component>
```

```
<section>
```

```
<id/>
```

```
<code/>
```

```
<effectiveTime/>
```

<!--This subject element contains all of the GUDID DI Record information.-->

```
<subject>
```

<!--classCode=MANU for the GUDID Submission, without this value, the XML may fail validation-->

```
<manufacturedProduct classCode="MANU">
```

```
<manufacturedProduct>
```

<!--Primary Device Identifier (required)-->

<!--code@code is the location of the Primary Device Identifier (DI), base package DI#101-->

<!-- code@codeSystem is the device-issuing-agency associated with the primary DI number

(below the OID for GS1 is shown)-->

```
<code code="101" codeSystem="1.3.160"/>
```

<!--The Trade Name/Brand name (required) -->

<!--The element is the free-text field for the Brand/Proprietary/Trade Name of the medical

device-->

```
<name>Trade Name/Brand Name</name>
```

<!--The Additional Product Description (optional)-->

```

<!--The desc element is the free-text description-->
<desc>add device description here</desc>
<!--The Device Model Number (required)-->
<asIdentifiedEntity>
  <!--id@root is a globally unique identifier assigned by the company for the model number--
>
  <!--id@extension is the company issued Device Model Number -->
  <!--code@code, C99285 is the code to indicate the type of Device Model, and C99286 for
Catalog Number -->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <id root="12345678-1234-1234-1234-123456789012" extension="Model T-1000"/>
  <code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
<!--The Catalog number for the device.-->
<asIdentifiedEntity>
  <!--id@root is a globally unique identifier assigned by the company for the catalog number-
->
  <!--id@extension is the company issued for the Catalog Number -->
  <!--code@code, C99285 is the code to indicate the type of Device Model, and C99286 for
Catalog Number -->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <id root="12345678-1234-1234-1234-123456789013" extension="Catalog-1000"/>
  <code code="C99286" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
<!--The FDA Product Code is Administrative data (one or more required)-->
<asSpecializedKind>
  <generalizedMaterialKind>
    <!--code@code is the 3-character Product Code (ABC is a placeholder)-->
    <!--codeSystem, 2.16.840.1.113883.3.150, is the OID for FDA Tracking Systems-->
    <!--The GUDID system will resolve the product code term and definition based on the
code provided.-->
    <code code="IRT" codeSystem="2.16.840.1.113883.3.150"/>
  </generalizedMaterialKind>
</asSpecializedKind>
<!--The GMDN Preferred Term Code (one GMDN PT Code is required)
>
<asSpecializedKind>
  <generalizedMaterialKind>
    <!--code@code is the 5-digit GMDN Preferred Term code (99999 is a placeholder)-->
    <!--code@codeSystem, 2.16.840.1.113883.6.276, is the OID for GMDN Agency-->
    <!--The GUDID system will resolve the Preferred Term based on the code provided.-->
    <code code="99999" codeSystem="2.16.840.1.113883.6.276"/>
  </generalizedMaterialKind>
</asSpecializedKind>
<!--The GMDN Preferred Term Code (one GMDN PT Code is required)-->
<asSpecializedKind>
  <generalizedMaterialKind>
    <!--code@codeSystem, 2.16.840.1.113883.6.303, is the OID for GMDN Agency-->
    <!--The GUDID system will resolve the Preferred Term based on the code provided.-->
    <code code="VSKK" codeSystem="2.16.840.1.113883.6.303"/>
  </generalizedMaterialKind>
</asSpecializedKind>
<!--The Additional or Alternative Device Identifiers (optional)-->
<!--Below is an example of a Secondary Device Identifier-->
<asEquivalentEntity>
  <!--code@code, C101724 is the code for Secondary Device Identifier)-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <code code="C101724" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <!--definingMaterialKind is the element used to provide the Secondary Device Identifier-->
  <!--code@code is the Secondary Device Identifier value-->
  <!--code@codeSystem, 2.16.840.1.113883.6.40 is the OID for HIBCC. The code system
must not be the same issuing agency as the one for the Primary Device Identifier - i.e., it needs to one of the other three options
available for the Secondary Device Identifier.-->
  <definingMaterialKind>
    <code code="H123456789" codeSystem="2.16.840.1.113883.6.40"/>
  </definingMaterialKind>

```

```

</asEquivalentEntity>
<asEquivalentEntity>
  <!--The Unit of Use Device Identifier is provided with the asEquivalentEntity element.-->
  <!--code@code, C101717 is the code for a Unit of Use Device Identifier-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <code code="C101717" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <!--definingMaterialKind indicates the Unit of Use Device Identifier-->
  <!--code@code is the Unit of Use Device Identifier Number-->
  <!--code@codeSystem 1.3.160, is the OID for GS1. Note that this codeSystem needs to
be the same codeSystem as provided for the Primary Device Identifier, otherwise it will not pass validation.)-->
  <definingMaterialKind>
    <code code="123456794830384" codeSystem="1.3.160"/>
  </definingMaterialKind>
</asEquivalentEntity>
<asEquivalentEntity>
  <!--The Direct Marking Device Identifier is provided with the asEquivalentEntity element.-->
  <!--code@code, C101678 is the code for a Direct Marking Device Identifier-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <code code="C101678" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <!--definingMaterialKind indicates the Direct Marking Device Identifier-->
  <!--code@code is the Direct Marking Device Identifier Number-->
  <!--code@codeSystem 1.3.160, is the OID for GS1. Note that this codeSystem needs to
be the same codeSystem as provided for the Primary Device Identifier, otherwise it will not pass validation.)-->
  <definingMaterialKind>
    <code code="123456794" codeSystem="1.3.160"/>
  </definingMaterialKind>
</asEquivalentEntity>
<!--Package Hierarchy #1, Configuration #1: DI#201, Quantity in Package=4, Package
type=carton, Package Discontinue Date=9/1/2014, Contains base package DI#101-->
<asContent>
  <quantity>
    <numerator value="100"/>
    <denominator/>
  </quantity>
  <containerPackagedProduct>
    <!--code@code is the device identifier value DI#= 201-->
    <!--code@codeSystem is the OID for the issuing agency for the device identifier, GS1
(1.3.160)-->
    <!--name is the package type, "carton"-->
    <!--capacityQuantity@value is the quantity per package, 4-->
    <code code="201" codeSystem="1.3.160"/>
    <name>carton</name>
    <capacityQuantity value="4"/>
    <asManufacturedProduct>
      <subjectOf>
        <marketingAct>
          <!--effectiveTime.high@value is the Package Device discontinued Date,
20140901-->
          <effectiveTime>
            <low/>
            <high value="20140901"/>
          </effectiveTime>
        </marketingAct>
      </subjectOf>
    </asManufacturedProduct>
    <!--Package hierarchy #1, Configuration #2: DI#301, Quantity in Package=5, Package
type=case, Package Discontinue Date=9/1/2014, Contains DI#-201-->
    <asContent>
      <containerPackagedProduct>
        <!--code@code is the device identifier value DI#= 301-->
        <!--code@codeSystem is the OID for the issuing agency for the device identifier,
GS1 (1.3.160)-->
        <!--name is the package type, "case"-->
        <!--capacityQuantity@value is the quantity per package, 5-->
        <code code="301" codeSystem="1.3.160"/>
        <name>case</name>
        <capacityQuantity value="5"/>
        <asManufacturedProduct>

```

```

                <subjectOf>
                    <marketingAct>
                        <!--effectiveTime.high@value is the Package Device
discontinued Date, 20140901-->
                            <effectiveTime>
                                <low/>
                                <high value="20140901"/>
                            </effectiveTime>
                        </marketingAct>
                    </subjectOf>
                </asManufacturedProduct>
            </containerPackagedProduct>
        </asContent>
    </containerPackagedProduct>
</asContent>
<!--Package Hierarchy #2, Configuration #3: DI#401, Quantity in Package=4, Package
type=carton, Package Discontinue Date=9/1/2014, Contains base package DI#101-->
<asContent>
    <quantity>
        <numerator value="100"/>
        <denominator/>
    </quantity>
    <!--code@code is the device identifier value DI#= 401-->
    <!--code@codeSystem is the OID for the issuing agency for the device identifier, GS1
(1.3.160)-->
        <!--name is the package type, "carton"-->
        <!--capacityQuantity@value is the quantity per package, 4-->
        <containerPackagedProduct>
            <code code="401" codeSystem="1.3.160"/>
            <name>carton</name>
            <capacityQuantity value="4"/>
            <asManufacturedProduct>
                <subjectOf>
                    <marketingAct>
                        <!--effectiveTime.high@value is the Package Device discontinued Date,
20140901-->
                            <effectiveTime>
                                <low/>
                                <high value="20140901"/>
                            </effectiveTime>
                        </marketingAct>
                    </subjectOf>
                </asManufacturedProduct>
            <asContent>
                <!--Package hierarchy #2, Configuration #4: DI#501, Quantity in Package=5,
Package type=case, Package Discontinue Date=9/1/2014, Contains DI#-401-->
                <!--code@code is the device identifier value DI#= 501-->
                <!--code@codeSystem is the OID for the issuing agency for the device identifier,
GS1 (1.3.160)-->
                    <!--name is the package type, "case"-->
                    <!--capacityQuantity@value is the quantity per package, 5-->
                    <containerPackagedProduct>
                        <code code="501" codeSystem="1.3.160"/>
                        <name>case</name>
                        <capacityQuantity value="5"/>
                        <asManufacturedProduct>
                            <subjectOf>
                                <marketingAct>
                                    <!--effectiveTime.high@value is the Package Device
discontinued Date, 20140901-->
                                        <effectiveTime>
                                            <low/>
                                            <high value="20140901"/>
                                        </effectiveTime>
                                    </marketingAct>
                                </subjectOf>
                            </asManufacturedProduct>
                        </containerPackagedProduct>
                    </asContent>
                </asContent>
            </asContent>
        </asContent>
    </asContent>

```

```

        </asContent>
      </containerPackagedProduct>
    </asContent>
  </manufacturedProduct>
</subjectOf>
  <document>
    <author>
      <assignedEntity>
        <representedOrganization>
          <assignedEntity1>
            <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <!--id@root,1.3.6.1.4.1.519.1 is the OID for Dun and Bradstreet-->
            <!--id@extension=DUNS number for the Labeler Organization to be
listed for the individual medical device.t-->
              <representedOrganization>
                <id root="1.3.6.1.4.1.519.1" extension="123456789"/>
              </representedOrganization>
            </assignedEntity1>
            <!--A phone number and email must be provided for each contactParty
element provided. The contactParty can be repeated as often as possible.-->
            <contactParty>
              <telecom value="tel:+1(999)999-1112" use="WP"/>
              <telecom value="mailto:info@device.com"/>
            </contactParty>
            <contactParty>
              <telecom value="tel:+1(999)999-1111" use="WP"/>
              <telecom value="mailto:info@device.com"/>
            </contactParty>
          </representedOrganization>
        </assignedEntity>
      </author>
    </document>
  </subjectOf>
  <!--Premarket Authorization Number-->
  <subjectOf>
    <approval>
      <!--id@root is the OID for the CDRH Tracking Systems (2.16.840.1.113883.3.150)-->
      <!-- the id@extension is the premarket approval/authorization number assigned by CDRH-->
      <!--code@code, C80441 is the code for a Premarket Approval-->
      <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
      <id root="2.16.840.1.113883.3.150" extension="P123456"/>
      <code code="C80441" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <!--The typeCode is a required attribute to pass schema validation. It should be set to
"COMP"-->
        <component typeCode="COMP">
          <approval>
            <!--code@code, C70862 is the temporary code for a Premarket Approval
supplement-->
              <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
              <id root="2.16.840.1.113883.3.150" extension="001"/>
              <code code="C70862" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            </approval>
          </component>
        </approval>
      </subjectOf>
      <subjectOf>
        <approval>
          <!--To provide a second authorization number with the same id.extension should be
contained in a new serialized element for approval. This follows the same instructions as the previous example.-->
            <id root="2.16.840.1.113883.3.150" extension="P123456"/>
            <code code="C80441" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <component typeCode="COMP">
              <approval>
                <id root="2.16.840.1.113883.3.150" extension="011"/>
                <code code="C70862" codeSystem="2.16.840.1.113883.3.26.1.1"/>
              </approval>
            </component>
          </approval>
        </subjectOf>
      </subjectOf>
    </approval>
  </subjectOf>

```

```

        </approval>
      </component>
    </approval>
  </subjectOf>
</subjectOf>
  <approval>
    <!--FDA Listing Number (As many listing numbers as applicable can be added)-->
    <!--id@root = 2.16.840.1.113883.3.150 is for FDA Tracking Systems Identifier-->
    <!--id@extension = FDA Listing Number-->
    <!--code@code, C101677 is the code for FDA Listing Number-->
    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
    <id root="2.16.840.1.113883.3.150" extension="D123456"/>
    <code code="C101677" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </approval>
</subjectOf>
<!--Production Identifier on Label - Serial Number (required)-->
<!--code@code, C101671 is the code for Controlled by Serial number-->
<!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
<!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
<!--value@value is True or False -->
</subjectOf>
  <characteristic>
    <code code="C101671" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
</subjectOf>
  <!--Production Identifier on Label - Lot or Batch Number (required)-->
  <!--code@code, C101672 is the code for Controlled by Lot Number-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
</subjectOf>
  <!--Production Identifier on Label - Expiration Date (required)-->
  <!--code@code, C101670 is the code for Controlled by Expiration Date-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C101670" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
</subjectOf>
  <!--Production Identifier on Label - Manufacturing Date (required)-->
  <!--code@code, C101669 is the code for Controlled by Manufacturing Date-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C101669" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
</subjectOf>
  <!--Production Identifier on Label - Donation Identification Number (required)-->
  <!--code@code, C113843 is the code for Donation Identification Number-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C113843" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>

```

```

        </characteristic>
    </subjectOf>
    <subjectOf>
        <!--Clinically Relevant Size is a characteristic that can either be sent with a CV or as free text.-->
>
        <characteristic>
            <!--code@code, C96684 is the code for longest diameter; clinically-relevant-size-type are
available for several known size measures. For testing, only select values are available in the controlled vocabulary. Additional
size types may be added in the future.-->
            <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
            <!--value@xsi:type is required to indicate the characteristic has a Physical Quantity data
type-->
            <!--value@value is the measurement value -->
            <!--value@unit is the unit of measurement -->
            <code code="C96684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <value xsi:type="PQ" value="3" unit="m"/>
        </characteristic>
    </subjectOf>
    <subjectOf>
        <!--Clinically Relevant Size - free text-->
        <!--code@code, C106041 is the temporary code for providing a free-text clinically-relevant-size.
For testing, this should be used when size-types are not available in the controlled vocabulary.-->
        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
        <!--value@xsi:type is required to indicate the characteristic has a String data type-->
        <!--value element should include the free-text between the value tags, as shown -->
        <characteristic>
            <code code="C106041" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <value xsi:type="ST">Size text</value>
        </characteristic>
    </subjectOf>
    <subjectOf>
        <!--Storage and Handling Requirements (Provide as many as necessary)-->
        <!--code@code, C101707 is the code for Storage Environment Temperature; storage-handling-
conditions are available. For testing, only select values are available in the controlled vocabulary. Additional storage and handling
conditions may be added in the future.-->
        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
        <!--value@xsi:type is required to indicate the characteristic has a Physical Quantity Interval
data type-->
        <!--value.low@value is the measurement value; provide when temperature has a range, provide
when the value is less than this value or if the value is exactly this temperature (note- same value will be entered in high@value)-->
        <!--value.low@unit is the unit of measurement -->
        <!--value.high@value is the measurement value; provide when temperature has a range,
provide when the value is greater than this value or if the value is exactly this temperature (note- same value will be entered in
low@value)- -->
        <!--value.high@unit is the unit of measurement -->
        <characteristic>
            <code code="C101707" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <value xsi:type="IVL_PQ">
                <low value="0" unit="Cel"/>
                <high value="10" unit="Cel"/>
            </value>
        </characteristic>
    </subjectOf>
    <subjectOf>
        <!--Special Storage Condition Text (provide as many as necessary)-->
        <!--code@code, C101704 is the code for providing a free-text special-storage-condition. For
testing, this element should be used when storage-requirements are not available in the controlled vocabulary.-->
        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
        <!--value@xsi:type is required to indicate the characteristic has a String data type-->
        <!--value element should include the free-text between the value tags, as shown -->
        <characteristic>
            <code code="C101704" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            <value xsi:type="ST1">keep out of sunlight</value>
        </characteristic>
    </subjectOf>
    <subjectOf>
        <!--Sterilization - Is the product packaged as sterile? (required)-->
        <!--code@code, C101676 is the code for Packaged as Sterile-->

```

```

<!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
<!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
<!--value@value is True or False -->
<characteristic>
  <code code="C101676" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  <value xsi:type="BL" value="true"/>
</characteristic>
</subjectOf>

<!--Sterilization Method – the "Requires sterilization prior to use" (code=C84382) is derived by the
existence or absence of a sterilization method. When a sterilization method code is provided (e.g.,
C101712- Dry Heat) and matches the sterilization values - then the question – "Requires sterilization
prior to use" will be marked "True". If this element (code=C84382) is not present, the question
"Requires sterilization prior to use" will be marked "False". -->
<!--code@code, C84382 indicates the package needs to be sterilized prior to use-->
<!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
<subjectOf>
  <characteristic>
    <code code="C84382" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <!--value@xsi:type is required to indicate the characteristic has a Coded data type-->
    <!--value@code, C101676 is the code for Sterilization Method. sterilization-method values
are available as per the regulations. Below the sample has C101712- Dry Heat as an example-->
    <!--value@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
    <value xsi:type="CD" code="C101712" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </characteristic>
</subjectOf>
<subjectOf>
  <!--Labeled as Containing Natural Rubber Latex (required)-->
  <!--code@code, C101673 is the code for Labeled as Containing Natural Rubber Latex-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C101673" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
<subjectOf>
  <!--Not Made with Natural Rubber Latex-->
  <!--code@code, C106038 is the code for -->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C106038" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
<subjectOf>
  <!--Single Use (required) -->
  <!--code@code, C53602 is the code for Single Use-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <characteristic>
    <code code="C53602" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
<!--HCT/P-->
<!--code@code, C101674 is the code for HCT/P-->
<!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI!-->
<!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
<!--value@value is True or False -->
<subjectOf>
  <characteristic>
    <code code="C101674" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>

```

```

    </characteristic>
  </subjectOf>
  <!--Kit-->
  <!--code@code, C50021 is the code for Kits-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <subjectOf>
    <characteristic>
      <code code="C50021" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <value xsi:type="BL" value="false"/>
    </characteristic>
  </subjectOf>
  <!--Combination Product-->
  <!--code@code, C54696 is the code for Combination Products-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <subjectOf>
    <characteristic>
      <code code="C54696" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <value xsi:type="BL" value="false"/>
    </characteristic>
  </subjectOf>
  <!--DM Exempt-->
  <!--code@code, C101679 is the code for DM Exempt-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <subjectOf>
    <characteristic>
      <code code="C101679" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <value xsi:type="BL" value="false"/>
    </characteristic>
  </subjectOf>
  <!--MRI Safety-->
  <!--code@code, C106044 is the code for MRI Safety-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <subjectOf>
    <characteristic>
      <code code="C106044" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <!--value@xsi:type is required to indicate the characteristic has a Code data type-->
      <!--value@code is the code value for the MRI Safety Status (MR Safe (C106045), MR
Unsafe (C106047) or MR Conditional (C106046))-->
      <!--value@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
      <value xsi:type="CD" code="C106045" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    </characteristic>
  </subjectOf>
  <!--Prescription Use (RX)-->
  <!--code@code, C28180 is the code for Prescription Use-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <subjectOf>
    <characteristic>
      <code code="C28180" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <value xsi:type="BL" value="true"/>
    </characteristic>
  </subjectOf>
  <!--Over the Counter (OTC)-->
  <!--code@code, C54068 is the code for Over the Counter-->
  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCI-->
  <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
  <!--value@value is True or False -->
  <subjectOf>
    <characteristic>
      <code code="C54068" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <value xsi:type="BL" value="true"/>
    </characteristic>
  </subjectOf>

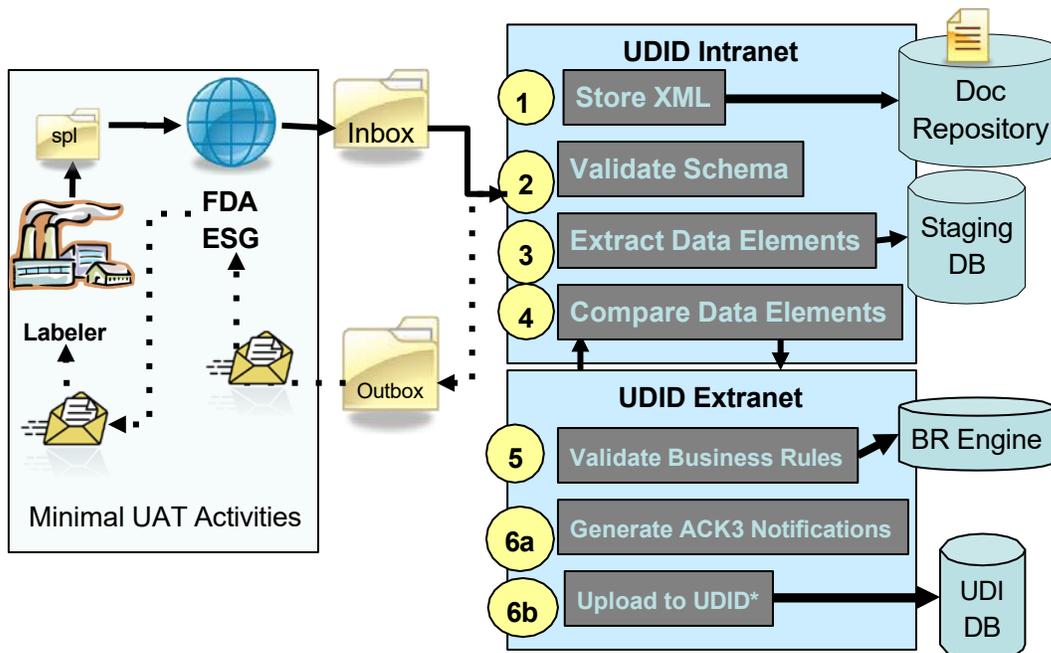
```

```
        </characteristic>  
      </subjectOf>  
    </manufacturedProduct>  
  </subject>  
</section>  
</component>  
</structuredBody>  
</component>  
</document>
```

APPENDIX: BUSINESS RULES

The following table outlines the business rules implemented for GUDID HL7 SPL Submission. This is a consolidated list of business rules that will be used to determine compliance at each of the SPL Process Steps. The figure below shows each of the steps in relation to the complete submission processing. Each Step results in a potential failure step – i.e., the ACK3 notification will be specific to the last successful process step.

Figure: SPL Process Steps



6.1 Business Rules – Step 1: Store XML

ID	SPL Step	Module/Category	Validation Error
GUDID-100001	Step 1	Store XML	<p>This CDRH submission has failed during initial processing. The main reasons for initial failure usually include –</p> <ol style="list-style-type: none"> (1) an incorrectly packaged submission, (2) an xml file was not detected in the packaged submission, (3) the submitted file type is not supported, and/or (4) missing information - the system could not determine the submission type due to a lack of information within the XML file. <p>Please review your submission and make any necessary updates prior to resubmitting via the FDA ESG.</p> <p>For questions regarding GUDID submissions, please visit http://www.fda.gov/udi and click on 'FDA UDI Help Desk'.</p>

6.2 Business Rules – Step 2: Validate Schema

ID	SPL Step	Module/Category	Validation Error
GUDID-200001	Step 2	Validate Schema	Unable to parse XML. Note: Any violation of well-formed XML will be caught at this step. Ensure that your XML validates against the GUDIDSPL.xsd schema file. The XSD file includes patterns for several attributes and these will fail schema validation.
GUDID-200002	Step 2	Duplicate Submission	A submission with the same Document identifier, Primary DI, setID and version are rejected as duplication. E.g., “GUDID SPL submission already exists, submission is duplicate.”
GUDID-200003	Step 2	Folder Requirements	SPL submission with core id <CoreID> is invalid. Submission folder cannot contain more than one file.

6.3 Business Rules – Step 3: Extract Data Elements

ID	SPL Step	Module/Category	Validation Error
GUDID-300001	Step 3	Invalid attribute value	Invalid value is provided for any of the attributes in the XML. E.g., Unable to extract value for <>
GUDID-300002	Step 3	Input Length Constraints	Refer to the SPL Code List document for data type and lengths of each data element. If the input value exceeds the database constraints, the submission will be rejected at Step 3.
GUDID-300003	Step 3	Input Format Requirements	If the input format (see Section 5.1.6.4.1) is not followed – e.g., email or phone formats, the submission will be rejected at Step 3.
GUDID-300004	Step 3	Required Boolean values	Refer to the Input constraints (i.e., values of “true” or “false”) or Schema requirements for the required Boolean elements. E.g., “Required Element Missing, Boolean value should be provided.”

ID	SPL Step	Module/Category	Validation Error
GUDID-300005	Step 3	Invalid Code values	Invalid code values provided will result in a failure at Step 3. E.g., “Unable to convert <Code>”. Refer to the SPL Code List document for valid codes or “Not a valid sterilization method.”
GUDID-300006	Step 3	Invalid Unit of Measure	Invalid Unit of Measure for the size type or storage and handling will result in a failure at Step 3. E.g., Not a valid unit of measure
GUDID-300007	Step 3	Valid Characteristic Code Values	The C-codes are used to determine the type of “characteristic” provided in the XML. Characteristic elements can be Boolean, Code values, Physical Quantities or Range, and string values.
GUDID-300008	Step 3	Valid OIDS	The OID is used to determine “asSpecializedKind” values for FDA Product Codes and GMDN Preferred Terms.
GUDID-300009	Step 3	Valid “asIdentifiedEntity” Code values	The C-codes are used to determine the type of “asIdentifiedEntity” values for the Version or Model Number and Catalog Number.
GUDID-300010	Step 3	Valid “asEquivalentEntity” Code values	The C-codes are used to determine the type of “asEquivalentEntity” values for Direct Marking, Secondary and Unit of Use Device Identifiers.
GUDID-300010	Step 3	FDA Listing Identifier	The FDA Listing number is implemented as an identifier value to be in line with Agency implementations of SPL. The id@root value is an OID for the FDA Tracking System and id@extension is the value assigned by CDRH. Note: id@root are typically UUIDs, but in the case where a namespace provides the identifier value, the OID is used.

6.4 Business Rules – Step 4: Compare Data Elements

ID	SPL Step	Module/Category	Validation Error
GUDID-400001	Step 4	Submitter Authentication	The Company with Duns number: <Submitter DUNS Number> is not authorized to submit for DUNS <Labeler DUNS Number>
GUDID-400002	Step 4	Submitter Authentication	If the incorrect Submitter code is associated with the Submitter DUNS number, the submission will be rejected. The Submitter type is checked and must match what is in the database.

ID	SPL Step	Module/Category	Validation Error
GUDID-400003	Step 4	Document ID	If a SPL Submission is sent with an existing document identifier and different setID and version number, the submission will be rejected. E.g., “Document id has already been used.”
GUDID-400004	Step 4	Required Elements	<Data element> is required. Note: All data elements required in the GUDID will fail at Step 4 if they are not provided in the XML. Refer to the GUDID Guidance to Industry, Appendix B for required elements.
GUDID-400005	Step 4	Document Updates	If a SPL Submission is sent with a new document identifier and an existing setID and version number, the submission will be rejected. E.g., “The setId and version number already exist.”
GUDID-400006	Step 4	Primary DI and Set Id	The Primary DI Record already exists for another DI Record
GUDID-400007	Step 4	Package DI	The Package identifier has already been used in this submission

6.5 Business Rules – Step 5: Validate Business Rules

Note: The GUDID system normalizes data and messages may indicate values that were transformed after receipt of SPL submission. For example, value of “true” is transformed to “Y” and “false” to “N”.

ID	SPL Step	Module/Category	Sample Message
GUDID-500001	Step 5	Grace Period	The device with primary device identifier <DI Number> is currently published or manually unpublished and cannot be unpublished via SPL
GUDID-500002	Step 5	Brand Name	The brand name cannot be greater than 80 characters
GUDID-500003	Step 5	Brand Name	Brand name is required
GUDID-500004	Step 5	DI Contact Email	The contact email cannot be greater than 100 characters
GUDID-500005	Step 5	DI Contact Email	Contact email is required
GUDID-500010	Step 5	DI Contact Phone Number	The contact phone cannot be greater than 20 characters

ID	SPL Step	Module/Category	Sample Message
GUDID-500011	Step 5	DI Contact Phone Number	Contact phone is required
GUDID-500014	Step 5	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Contains latex should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500015	Step 5	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Contains latex is required
GUDID-500016	Step 5	Production Identifier in UDI – Expiration Date	Production Identifier Expiration Date should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500017	Step 5	Production Identifier in UDI – Expiration Date	Production Identifier Expiration Date is a required data element
GUDID-500018	Step 5	Production Identifier in UDI – Lot or Batch Number	Production Identifier Lot flag should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500019	Step 5	Production Identifier in UDI – Lot or Batch Number	Production Identifier Lot flag is a required data element
GUDID-500020	Step 5	Production Identifier in UDI – Manufacturing Date	Production Identifier Manufacture Date should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500021	Step 5	Production Identifier in UDI – Manufacturing Date	Production Identifier Manufacture Date is a required data element
GUDID-500022	Step 5	Production Identifier in UDI – Serial Number	Production Identifier Serial number should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500023	Step 5	Production Identifier in UDI – Serial Number	Production Identifier Serial number is a required data element

ID	SPL Step	Module/Category	Sample Message
GUDID-500026	Step 5	DUNS Number	The DUNS number associated with this device cannot be greater than 9 characters
GUDID-500027	Step 5	MRI Safety	The device MRI safety code cannot be greater than 6 characters
GUDID-500029	Step 5	Combination Product	The Device combination product flag should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500030	Step 5	Combination Product	The device combination product flag cannot be greater than 1 character
GUDID-500031	Step 5	HCT/P	Device contains human tissue should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500032	Step 5	DI Device Count	The device count must be an integer greater than zero
GUDID-500033	Step 5	DI Device Count	The device count is required
GUDID-500034	Step 5	DI Device Count	The device count cannot be an integer greater than 9999999
GUDID-500035	Step 5	DI Description	The device description cannot be greater than 2000 characters
GUDID-500036	Step 5	Exempt Device	The device exempt from premarket authorization flag cannot be greater than 1 character <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500037	Step 5	Exempt Device	Device exempt from premarket authorization should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500038	Step 5	DI	A device id is required
GUDID-500039	Step 5	Kit	The device kit flag should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>

ID	SPL Step	Module/Category	Sample Message
GUDID-500040	Step 5	Kit	The device kit flag cannot be greater than 1 character
GUDID-500043	Step 5	Model Number	The device model cannot be greater than 80 characters
GUDID-500044	Step 5	Package	A device package quantity is required
GUDID-500045	Step 5	Package	The device package quantity must be an integer greater than zero
GUDID-500046	Step 5	DI Type	A device type code is required Note: The code value for DI Type (i.e., Unit Of Use, DM DI or Secondary DI) must be provided.
GUDID-500047	Step 5	Document Id	The Document ID associated with this device cannot be greater than 40 characters
GUDID-500048	Step 5	DI Contact Phone Number	The domestic phone number for contact has an invalid format
GUDID-500049	Step 5	DI	The package device identifier <package DI> is a duplicate
GUDID-500050	Step 5	FDA Listing	The FDA listing number <FDA listing number> does not exist
GUDID-500051	Step 5	FDA Listing	At least one valid FDA listing number is required.
GUDID-500052	Step 5	Single Use	For single use flag should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of "Y" or "N".</i>
GUDID-500053	Step 5	GMDN	The GMDN code <code> does not exist
GUDID-500054	Step 5	DI	The device identifier for issuing agency <issuing agency name> must be numeric digits between 12 to 14 characters
GUDID-500055	Step 5	DI	The device identifier for issuing agency HIBCC must be 6-23 character alphanumeric value, first character alphabetic and last character numeric, and cannot include special characters.

ID	SPL Step	Module/Category	Sample Message
GUDID-500056	Step 5	DI	The device identifier for issuing agency <issuing agency name> cannot be greater than 25 characters
GUDID-500057	Step 5	DI Contact Phone Number	The international phone number for contact has an invalid format
GUDID-500058	Step 5	DI	<DI Type Code> is an invalid Device Identifier Type Code
GUDID-500059	Step 5	DI Contact Email Format	<email address> is not valid email.
GUDID-500063	Step 5	DM DI	Multiple Direct Marking Device Identifier are not allowed
GUDID-500064	Step 5	Primary DI	Multiple Primary Device Identifier not allowed
GUDID-500065	Step 5	Unit of Use DI	Multiple Unit of Use Device Identifiers are not allowed
GUDID-500066	Step 5	Premarket Authorization Number	The premarket number <submission number> does not exist
GUDID-500067	Step 5	DM DI	The Direct Marking device identifier <device identifier> should have the same issuing agency as the primary device identifier <primary DI>
GUDID-500068	Step 5	Package DI	The Direct Package device identifier <device identifier> should have the same issuing agency as the primary device identifier <primary DI>
GUDID-500069	Step 5	Secondary DI	The secondary device identifier <device identifier> should not have the same issuing agency as the primary device identifier <device identifier>.
GUDID-500070	Step 5	Unit of Use DI	The Unit of Use device identifier <device identifier> should have the same issuing agency as the primary device identifier <device identifier>.
GUDID-500071	Step 5	Primary DI	A primary device identifier is required
GUDID-500072	Step 5	FDA Product Code	The product code <product code> does not exist.
GUDID-500073	Step 5	DI Record Publish Date	Publish date must be after <date>.

ID	SPL Step	Module/Category	Sample Message
GUDID-500074	Step 5	DI Record Publish Date	Publish date is required
GUDID-500075	Step 5	Secondary DI	The Secondary device identifier <device identifier> must be numeric digits between 1 to 10.
GUDID-500076	Step 5	Core ID	The Submission core id cannot be greater than 50 characters
GUDID-500077	Step 5	Document Id	The Submission document id cannot be greater than 40 characters
GUDID-500078	Step 5	Document Id	The Submission document id required
GUDID-500079	Step 5	Primary DI	The Submission primary device id cannot be greater than 25 characters
GUDID-500080	Step 5	Set Id	The Submission set id cannot be greater than 40 characters
GUDID-500081	Step 5	Set Id	The Submission set id is required
GUDID-500082	Step 5	version number	A Submission version number or higher already exist
GUDID-500083	Step 5	version number	The Submission version number is required
GUDID-500084	Step 5	version number	The Submission version number cannot be an integer greater than 99999
GUDID-500085	Step 5	Unpublish Flag	The User unpublished flag should have a value of either T or F
GUDID-500086	Step 5	Unpublish Flag	The user unpublished flag cannot be greater than 1 character
GUDID-500087	Step 5	Duplicate DI	The device identifier <DI Number> is a duplicate.
GUDID-500088	Step 5	Duplicate DI	The following device identifiers are already in use: [DI Number(s)]
GUDID-500089	Step 5	Kits and Licensed IVD	At least one valid Product Code is required because kit is not selected and Licensed IVD not provided
GUDID-500090	Step 5	Unit of Use DI	The Unit of Use DI cannot be provided when the device count is equal to 1

ID	SPL Step	Module/Category	Sample Message
GUDID-500091	Step 5	HCT/P	If the device contains human tissue then the premarket authorization number < > must begin with P, K, H, BP, BK, or BH.
GUDID-500092	Step 5	HCT/P	If the device contains human tissue then the premarket exempt cannot be selected.
GUDID-500093	Step 5	Direct Marking Device Identifier Number	DM DI and "Device Subject to Direct Marking (DM), but Exempt" cannot both exist.
GUDID-500094	Step 5	Commercial Distribution End Date and Package Date	The package discontinued date <Date> must be less than or equal to the Commercial Distribution end date <Date> for the medical devices base package or higher level package.
GUDID-500095	Step 5	Commercial Distribution End Date and Package Discontinue Date	The package Date Device Discontinued date must the less than or equal to the Date Device Discontinued date <Date> for the medical device's base package
GUDID-500096	Step 5	HCTP and Kit	If HCT/P and Kit are selected then a premarket number is required
GUDID-500097	Step 5	Submission Updates	A Submission version number or higher already exist
GUDID-500098	Step 5	Supplement Number	The Premarket Authorization number <Submission Number> has an invalid supplement format
GUDID-500099	Step 5	Grace Period Expiration	The device information cannot be updated because the grace period has expired and fields that trigger a new Device Identifier has changed
GUDID-500100	Step 5	Valid Units of Measure	The Product size with size type code <code> and unit of measure <unit of measure value> is an invalid combination
GUDID-500101	Step 5	Listing Number	Inactive Listing Number cannot be added to a DI record
GUDID-500102	Step 5	Listing Number	The SPL submission needs to have at least one active FDA listing number if anything other than Package Device Identifiers and Commercial Distribution End Date need to be added or modified

ID	SPL Step	Module/Category	Sample Message
GUDID-500103	Step 5	Secondary DI	The Secondary device identifier <Secondary DI value> with issuing agency NDC/NHRIC must be 10 or 11 digits in 3 segments with 2 hyphens. Valid formats for 10-digit values are XXXX-XXXX-XX, or XXXXX-XXX-XX, or XXXXX-XXXX-X. The valid format for an 11 digit value is XXXXX-XXXX-XX
GUDID-500104	Step 5	Previous DI	Invalid or non-existing Previous Device Identifier
GUDID-500105	Step 5	Previous Device Identifier	Previous Device Identifier cannot be the same as Primary DI
GUDID-500106	Step 5	Previous Device Identifier	Multiple Previous Device Identifiers are not allowed
GUDID-500107	Step 5	DUNS Number	The DUNS Number <DUNS Number value> does not exist
GUDID-500108	Step 5	Production Identifier in UDI – Donation Identification Number	Production Identifier Donation Identification Number should have a value of either Y or N <i>Note: the Boolean value is converted to the database value of “Y” or “N”.</i>
GUDID-500109	Step 5	Production Identifier in UDI – Donation Identification Number	Production Identifier Donation Identification Number is a required data element
GUDID-500110	Step 5	MRI Safety	The device MRI safety code is required
GUDID-500111	Step 5	Catalog Number	Catalog number cannot be greater than 80 characters
GUDID-500112	Step 5	Premarket Authorization Number and Premarket Exempt Number	Premarket Authorization Number and Premarket exempt flag both cannot be provided
GUDID-500113	Step 5	Existing DI record	The device information cannot be updated via SPL since it's within the grace period and the record was initially created via the web