GUDID HL7 SPL Submissions – Testing Requirements for Production Submissions

All GUDID HL7 SPL files must come through the FDA Electronic Submissions Gateway (ESG) (www.fda.gov/esg). Prior to submitting to production GUDID, Labelers and/or Third-Parties must pass a set of tests in the Pre-Production environment, for both the ESG and GUDID.

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. As such, we encourage you to do testing that closely mimics real world scenarios applicable to your devices as there are many business rules that may affect the success of the submission. Please be sure your testing includes all changes to DI records during the lifecycle of your device before requesting access to the production environment. Just completing the test scenarios listed below is not considered adequate testing.

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.
  o 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.
  o Upon completion of ESG testing, ESG will provide a production ESG account. Please do not use the ESG Production account to submit GUDID HL7 SPL submissions until you complete GUDID HL7 SPL testing as indicated below.
• Once your ESG Pre-production account is established and you complet ESG testing, please complete GUDID HL7 SPL testing using your FDA ESG Pre-production account .
  o Request a GUDID Pre-production (test) account, visit www.fda.gov/udi for more information.
  o Once a GUDID test account is established, you can begin GUDID HL7 SPL submission testing.
  o Complete thorough internal testing
  o 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.
  o 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:
      – CoreID[1] and Primary DI Number
      – For Scenario 1a, 2a and 3a, GUDID Data Elements changed, value before change and value after change
  o The FDA UDI staff will review the information and indicate next steps for production HL7 SPL submissions.

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

Test Scenario	Test Description	Changes/Updates	Success Criteria
Scenario 1	Create a new DI record with today's publish date		DI record is uploaded to GUDID as a **Published** DI record.
Scenario 1a	Update the newly created record **during** grace period.

(Note: Grace Period in the preproduction (test) GUDID environment starts the day after a DI record is published and is set to 1 day) | Change any of the following data elements: Brand Name, Version or Model Number, For Single Use, Latex information, or MRI Safety information. | DI record is updated correctly. |
| **Scenario 2** | Create a new DI record with a future publish Date. Must include a Premarket Submission Number. | | DI Record is uploaded to GUDID as an **Unpublished** DI record. |
| **Scenario 2a** | Update the newly created record. | Change DI Record Publish Date to today's date.

Add another FDA Premarket Submission Number. | DI record is updated correctly - DI record status shows as **Published**, and new Premarket Submission Number is added correctly. |
| **Scenario 3** | Create a new DI record with today's publish date. The DI record must include a package hierarchy. | | DI record is uploaded to GUDID as a **Published** DI record and the package hierarchy is reflected correctly. |
| **Scenario 3a** | Update the newly created record **after** grace period.

(Note: Grace Period in the preproduction (test) GUDID environment starts the day after a DI record is published and is set to 1 day) | Add/Change the following data elements: Commercial Distribution End Date, Storage and Handling information, Clinically Relevant Size information. | DI record is updated correctly. |