

Steps to GUDID HL7 SPL Submission

The HL7 SPL Submission option enables companies to electronically submit device information one Device Identifier (DI) record at a time as an HL7 SPL xml file. All GUDID HL7 SPL files must come through the FDA Electronic Submissions Gateway.

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.

Companies that plan to use the HL7 SPL submission option will need to do the following:

Review [UDI guidance documents and resources](#) to gather and prepare your data for GUDID submissions.

1. Gather data required for GUDID DI records based on the GUDID [Data Elements Reference Table](#).
2. Review HL7 SPL submission testing requirements and processes provided in the [HL7 SPL Implementation Files](#).

Request a [Pre-Production GUDID Account](#).

1. Allocate 2-3 weeks for completion.
2. Complete request accurately to prevent account creation delays.
3. Refer all questions concerning UDI or GUDID to the [FDA UDI Help Desk](#).

Request an [FDA Electronic Submissions Gateway](#) (ESG) Account to submit HL7 SPL files (4 Weeks).

1. Contact the [ESG Help Desk](#) for ESG [account process and any other ESG](#) related inquiries.
2. FDA ESG automatically routes .XML files to the GUDID; it does not open or review submissions.
3. FDA ESG will provide an ESG production account upon completion of GUDID testing.

Once ESG and GUDID Pre-Production accounts are established:

3. Complete GUDID testing in addition to the test scenarios -specified in 'GUDID_TestCriteriaProduction.pdf' in the [HL7 SPL Implementation Files](#).
1. Review your records. Log in to your GUDID Pre-Production Account, view and verify that your records are loaded correctly.
2. Send the following Information to the [FDA UDI Help Desk](#) for review and production account approval:
 - a. For each test scenario:
 - i. CoreID
 - ii. Primary DI Number
 - iii. For Scenario 1a, 2a and 3a, GUDID Data Elements changed, value before change, and value after change.

After you successfully complete GUDID Pre-Production Testing, a GUDID production account will be established for GUDID submissions; an FDA Analyst will contact you with further instructions.

[Subscribe to the UDI mailing list](#) to be notified about updates for the UDI program.

[Subscribe to the GUDID mailing list](#) to be alerted to database changes and GUDID system status updates.