GUDID Account Request: Preparation and Process

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The GUDID

• Data submission required by UDI System Final Rule
• Submission must be made to the Global Unique Device Identification Database (GUDID)
• Data submission requires establishing a GUDID Account
• Request account at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUIDDatabaseGUDID/ucm416113.htm
Learning Objectives

• Understand the GUDID Account Request Process
• Prepare the necessary information to open your account
• Evaluate your GUDID submission options
• Understand the functions of the FDA UDI Help Desk
GUDID Roles - Entities

• Organization
  – Highest corporate level of company
  – Account is registered to this entity
  – Entity responsible for meeting data submission requirements

• Labeler
  – Name of company on the label
  – Entity responsible for submitting the data to the GUDID

• Third Party Data Submitter
  – May submit records on behalf of the labeler
GUDID Roles - Users

• Regulatory Contact
  – Responsible for GUDID submission requirements
  – May be a third party

• Coordinator
  – Manages GUDID labeler accounts

• Labeler Data Entry (LDE) User
  – Submits required information for each device to the GUDID
The GUDID Account Request

- Editable PDF document
- Seven Sections
  - Labeler Organization
  - Regulatory Contact
  - GUDID Submission Option
  - Premarket Application Number
  - Labeler DUNS
  - Coordinator
  - Third Party Submitter (optional)
Labeler Organization Information

- Represents highest corporate level of the organization
- Includes
  - Organization’s Dun & Bradstreet Numbering System (DUNS) number (http://www.dnb.com/government/duns-request.html)
  - Name
  - Address
- GUDID pulls information from DUNS database
  - Contact Help Desk if information changes
Regulatory Contact Information

- Individual responsible for GUDID submission requirements
- May be an employee of the Organization or an authorized third party
- Designating a third party requires letter from your Organization stating:
  - which devices the third party will serve as contact
  - how long the third party will serve as contact
  - who will notify the FDA if the third party is modified or removed
GUDID Submission Option

- Two options:
  - Web Interface
  - Health Level 7 Structured Product Labeling (HL7 SPL) submission

- Web Interface option
  - Goes directly to production environment. Published records will be publicly visible.

- HL7 SPL option
  - Requires testing in pre-production environment. Pre-production records will not be publicly visible and do not satisfy UDI requirements.
  - Production access will be granted once testing is completed.
  - HL7 SPL accounts include web interface access
Web Interface

• Offers a form-based method for entering required device identification information
• Limited to one record per entry
• Requires less technical expertise
• Best option for users with small quantities of records
HL7 SPL

- Uses Extensible Markup Language (XML) schema to submit records
- Can publish multiple records simultaneously
- Must submit completed test results with production account request
- Requires separate account through FDA Electronic Submissions Gateway (ESG). [http://www.fda.gov/esg](http://www.fda.gov/esg)
- Requires more technical expertise
- Best option for users with large quantities of records
- Labelers may use a third party to submit on their behalf
FDA Premarket Application Number

• Method for validating labeler eligibility to open an account
• May provide: Premarket Approval (PMA), Premarket notification [510(k)], de novo classification, Humanitarian Device Exemption
• Do not provide FDA listing number
• Only one valid number is necessary to approve an account.
Labeler DUNS Number

• DUNS number of labeler who is responsible for submitting GUDID entries
• Used to identify the labeler for a version or model of a device
• Each device record must be associated with a labeler DUNS
• Labeler company name in DUNS should match what is listed on the device label
Coordinator Information

• Responsible for management of the GUDID account for a specified labeler DUNS
• Creates the Labeler Data Entry (LDE) user accounts in the GUDID that create and edit DI records
• Coordinator may also be an LDE user
• May be a member of the organization or a third party representative
Third Party Submitter Information

- Entities authorized to submit to the GUDID on behalf of a labeler
- Third parties may request pre-production accounts to test their services prior to submitting for clients
- Labeler organizations retain all data access capabilities
- Labeler organizations remain responsible for meeting data submission requirements
Steps for Success

• Ensure that all sections are completed
  • Third Party Submitter conditionally required
• Confirm accuracy of information in DUNS database for all labeler and organization DUNS numbers
• Identify individuals for each GUDID user role
• Verify that your device is part of one of the Classes open to GUDID entry
• Configure email accounts to accept responses from “@salesforce.com”
Help Desk

• Located at:  
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm

• Primary method to interact with UDI team

• Questions are submitted via website. Submission establishes an email correspondence with an assigned case number.
Help Desk Best Practices

• Complete contact information
• Submit a Help Desk inquiry for a single question
• Keep follow-up questions related to the original in the same email thread
• Submit a new Help Desk inquiry for new questions
• Use system generated auto response email to send attachments, if necessary
  • Ex: use to submit HL7 SPL test results
Summary

• Data must be submitted to the GUDID to comply with UDI rule requirements
• Establish an account to submit data, following defined procedures
• Choose best submission method for your needs
• Use the Help Desk for communicating with the UDI team
• All resources can be accessed at: http://www.fda.gov/udi
Providing Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules - videos, audio recordings, power point presentations, software-based “how to” modules
   - accessible on your portable devices: [http://www.fda.gov/Training/CDRHLearn](http://www.fda.gov/Training/CDRHLearn)

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics: [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance)

3. **Division of Industry and Consumer Education (DICE)**
   - If you have a question - Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9am – 12:30 pm; 1-4:30 pm EST)
   - Web Homepage: [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm)