

## **Slide 1 (Introduction)**

**Hello, my name is Chris Diamant and I am a UDI Program Analyst in the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health.**

## **Slide 2**

**The Unique Device Identification system final rule requires labelers of medical devices placed into U.S. commercial distribution to submit certain device identification data for their devices to the FDA. This data is submitted to the Global Unique Device Identification Database, which we call the GOOD ID.**

**But before labelers can submit device records to the GUDID, their organization must first request a GUDID account using the link provided on this slide.**

## **Slide 3**

**In this presentation, I will help you:**

**Understand the GUDID account request process.**

**Prepare the necessary information to open your account and make successful data submissions**

**Evaluate your GUDID data submission options, choosing the right one for your organization's needs; and**

**Understand how to use the FDA UDI Help Desk to request an account and also to ask the UDI team any questions you may have about UDI requirements.**

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**Before we discuss the account request process, it is important to understand the roles within the GUDID system since this information will be needed to set up your account. This slide shows the roles of business entities.**

**First is the organization. This is the highest corporate level of a company. The GUDID account is registered to the organization. It is the organization that is ultimately responsible for meeting the data submission requirements for a particular device.**

**Next, is the labeler, which is the company or firm whose name appears on the device label. It is responsible for submitting the data to the GUDID, and its name and address is associated with the device record in the database.**

**Organizations may choose to use third party submitters to submit records on a labeler's behalf. This process will be discussed later in the presentation.**

**Note that an entity may serve more than one role for an account. You may change information about labelers and third parties after you establish your account.**

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**Individuals also have roles. The regulatory contact is the person responsible for ensuring the organization is complying with their GUDID submission requirements. This role may be filled by a third party representative, if the organization chooses.**

**The account coordinator manages the GUDID labeler accounts. They also create and manage the Labeler Data Entry user accounts. LDE users submit the required information for each device to the GUDID.**

**Note that an individual may serve more than one role for an account. You may change the people designated for a given role after you establish your account.**

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**The GUDID Account Request consists of a three page Adobe PDF document. It needs to be requested through the link provided on slide two, which is part of the UDI website. It is configured to be editable, and we urge all account applicants to complete their application electronically. This will prevent transcription errors by the applicant or the FDA data analyst handling the request.**

**The Account Request is divided into seven sections. They are the labeler organization, regulatory contact, GUDID submission option, premarket application number, labeler DUNS, coordinator, and third party submitter, if applicable.**

**Now, I'm going to talk about the information needed in each section, starting with the Organization**

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**As I mentioned, the labeler's Organization represents the highest corporate level of the business. An organization may have more than one labeler associated with their account. All organizations must have a Dun and Bradstreet Numbering System (DUNS) number. Please see the provided link for more information. The DUNS number for the organization may represent the location of headquarters, or**

may be the parent DUNS for labelers that are part of the organization requesting the account.

When you go to submit device records, the GUDID will automatically pull the labeler's name and address for a given record from the DUNS database, so keeping your organization's DUNS information up to date is crucial to providing accurate device identification through the GUDID.

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Next is the regulatory contact. Again, this is the individual responsible for ensuring that your organization is meeting their GUDID submission requirements. They will be the point of contact for communications from the FDA to your organization.

The regulatory contact may be a member of your organization, or a third party that you choose to represent you. If you choose to delegate contact duties to a third party, you will need to provide a letter from an authorized member of your organization on company letterhead as part of your account request, stating for which devices the third party will serve as contact how long the third party will serve as contact, and who will notify the FDA in case the third party is modified or removed

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Next, choose your data submission option. The GUDID offers two methods for submission: via web interface or the Health Level 7 Structured Product Labeling standard.

The Web interface option goes directly to the production environment. Device records may be created and published at any time after getting your account. When records are published, they are available for viewing and searching in the public facing portion of the GUDID.

To use the HL7 SPL submission option, you'll first need to establish an account in the pre-production testing environment. This testing allows you to ensure that your system is properly configured to make submissions to the GUDID. Pre-production records are not publicly visible, and do not satisfy the requirements of the UDI rule.

Once this testing is complete, you must then request a production account for your organization. Please note that the HL7 SPL production account also includes web access, and allows for data entries to be made through either method.

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The web interface environment is a form-based method for entering the required device identification information. You can only enter one record per entry. This method should be familiar to users who have experience using web based services, and may be easier for users with less technical expertise. Since web interface accounts don't require pre-production testing, they should be the best option for labelers who expect to submit a small number of records.

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The HL7 SPL environment is an extensible markup language (XML) based submission method. It relies on XML schema to format information for submission through the FDA Electronic Submissions Gateway (ESG). The HL7 SPL process allows entry of multiple records simultaneously.

All users of this method must establish an account through the ESG service. The ESG account is separate from your GUDID account and is not administered by the UDI team but is required to submit HL7 SPL records.

Because the HL7 SPL submission requires more technical expertise, and adds steps to the submission process, we recommend this method for users who are submitting a large number of records. Also note that labelers may use a third party to submit device records on their behalf.

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In the next section of the account request, provide a valid FDA Premarket number for a currently marketed device. We are allowing labelers to get GUDID accounts based on UDI compliance dates, which are phased in by class of device. We need the premarket number to validate that a labeler is eligible to open an account. This section of the account request lists the classes of devices currently able to submit to the GUDID, and is updated as new classes become eligible.

Labelers may provide any of the following premarket numbers: Premarket approval (PMA), Premarket notification (510k), De Novo classification, or Humanitarian Device Exemption. FDA Listing numbers are not valid entries.

Additionally, since the premarket number is only used to validate submission eligibility, only one valid number must be provided on the account request.

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As we've discussed, every organizational account must designate at least one labeler entity. The labeler DUNS number is the DUNS number of the labeler who is responsible for submitting to the GUDID for a particular device. This may be the

same DUNS number as the organization applying for a GUDID account, or a different DUNS if the labeler is not the same as the organization.

Again, when it comes to submitting actual device records, you will need to provide the labeler DUNS to identify the labeler associated with a particular device record. And the company name for that DUNS number should match what is on the device label.

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The next section requires you to list coordinator information for your organization. These individuals are responsible for managing the GUDID account for a specified labeler DUNS. Each coordinator may be responsible for one or more labeler DUNS numbers, and the device records associated with them.

The coordinators are responsible for creating the labeler data entry (LDE) accounts. These are the individuals who can create and edit device records for each labeler DUNS. A coordinator may also serve as an LDE user.

Coordinators may work for the labeler organization or may be third party representatives. They may be added and removed at the discretion of the organization. Note that while coordinators can make changes to LDE users on their own, if your organization wants to change coordinators, you'll need to request that through the help desk.

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The final section of the account request allows a labeler to authorize a third party submitter. Third party submitters are entities authorized to submit to the GUDID on behalf of a labeler. The third party must follow the same testing procedures, even if the third party has done testing and submitted data for other labelers in the past.

Third parties may independently request pre-production accounts to test their IT services prior to submitting for a client or being designated as a third party on a labeler's account request. This allows a third party to do testing without a labeler, but we don't give third parties access to the production environment on their own behalf. The labeler organizations must still submit the required test results even if they are using a third party submitter who has already tested in the pre-production environment.

The labeler organization retains all data access capabilities and rights to the data submitted, and may change or stop using a third party at any time. Again organizations are ultimately responsible for meeting the data submission requirements of the UDI rule.

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**Based on our experience with account requests, taking the following steps will help ensure a successful application and prompt access to the GUDID.**

**The first step is to ensure that all sections are completed. The third party section is only needed if you choose to use a third party instead of submitting data from the organization itself. Each section provides a narrative explanation of the information required, but if it remains unclear, please contact the UDI Help Desk.**

**The second step is to confirm the accuracy of your information in the DUNS database for all labeler and organization DUNS numbers associated with your account.**

**The third step is to identify individuals for each GUDID user role.**

**The fourth step is to verify that your device belongs to one of the classes open to GUDID entry. Only labelers of device classes currently open for data submission may request an account.**

**Last, to ensure help desk communications arrive correctly, please have your organization's requestor, regulatory contact, and coordinators configure their email filters to accept responses from the email domain shown on this slide.**

## **Slide 17**

**I want to spend just a few minutes talking about the FDA UDI help desk, which is the primary method for account requestors, or anyone, to interact with the UDI team. We get thousands of questions every year about UDI, and funneling questions through the help desk allows us to keep track of all the questions, and make sure that you get the right answer to your question as promptly as possible. The web location for the help desk is displayed on this slide. For any requests or questions you have regarding the process or any UDI-related issues, all you need to do is fill in the provided fields on the website and submit your inquiry.**

**Once your inquiry is received, you'll receive an automatically generated email response acknowledging receipt of your inquiry. This response will have a case number used to track responses and follow ups to your question.**

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**The help desk will serve as your point of contact with the UDI team. To get the best service, here are some best practices.**

**First, when submitting a help desk inquiry, please provide complete contact information. This allows us to track your submission history and ensures that we can easily find prior submissions.**

**Second, submit a help desk inquiry for a single question whenever possible. This allows us to assign the inquiry to the person on the UDI team who can give you with the right answer in the shortest time.**

**Third, keep follow-up questions for a particular inquiry in the same email thread. This can be done by simply replying via email to the most recent email on that question that you received from the Help Desk.**

**Fourth, if you have a different question from one you sent in before, submit a new inquiry. That's because we may need to assign your new question to a different UDI team member than the one who handled your previous question. Opening a new inquiry ensures that your new question gets directed to the person who can give you the right response as quickly as possible.**

**Finally, if you need to send attachments with your inquiry, look for the system generated auto response email that you'll receive after you submit to the help desk. Then respond to the auto response email with your attachment, and the attachment will be added to the inquiry's case file. This is also the way you can submit your HL7 SPL test results if your organization chooses that submission method.**

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**In summary, remember that data submission to the GUDID is necessary to comply with the UDI rule requirements. Before you can submit GUDID data, you need to establish a GUDID account following the procedures we've just discussed. The GUDID offers two submission options, and you should choose the one that best suits your organization's needs. If you have any issues setting up your account, use the Help Desk to communicate with the UDI team.**

**We call upon you to use all links and resources for the UDI program, including links to the account request and already published guidance information which may be found at our website listed on this slide.**

**We look forward to working with you. Thank you for watching.**

### **Slide 20**

**This presentation and other helpful videos and educational resources can be found at CDRH Learn. For text-based information on premarket and postmarket topics, including how to bring a medical device to market, please visit Device Advice. For additional information on these or any other medical device**

**regulatory topics, feel free to contact the Division of Industry and Consumer Education.**