Food and Drug Administration

Center for Devices and Radiological Health

**Global Unique Device Identification Database (GUDID)
User Manual – Unlocking Device Records for Editing**
Version 1.0

Date: March 30, 2018

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Introduction

This purpose of this document is to provide information to device Labelers[1], entities responsible for providing device identification data to the GUDID (Global Unique Device Identification Database) regarding recent enhancements to GUDID. GUDID Release 2.2 enhancements, scheduled to be deployed on March 30, 2018, provide labelers the ability to "unlock" device records to efficiently manage their device identification data in GUDID and ensure its accuracy.

1. Background

When a GUDID DI record is initially submitted (either by manual data entry via the GUDID Web Interface or as a GUDID HL7 SPL submission) and published, the record starts the "grace period"[2].

- During the grace period, all DI record data element values may be edited, except the DI Record Publish Date. Labelers are encouraged to use the grace period as a review period to ensure their records are accurate and make any updates as needed.

- After the grace period passes, the record is released to the public on AccessGUDID and OpenFDA and DI record edits are restricted. Refer to the GUDID Data Elements Reference Table on www.fda.gov/udi for more information on which data elements may be edited after the grace period.

In practice, the grace period has not been utilized as intended. We have gotten frequent requests to assist labelers to correct data after the grace period, when the record has already been released to the public.

To ensure quality device identification information is available to the public, the ability to "unlock" a device record(s) for error correction after the grace period is being implemented as part of GUDID Release 2.2 enhancements.

Note that there have been no changes made with regards to New DI trigger data elements[3] or assignment of new Device Identifiers. The unlock functionality should not be used to submit edits to data elements when new Device Identifier assignment is necessary.

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[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] Currently, for Published DI records, the grace period is set to 30 calendar days and starts the day after the DI Record Publish Date. Note that the grace period duration may be changed in a future release.

[3] New DI trigger data elements are those, which when changed, no longer represent the same device and require a new Device Identifier to be assigned.

1.1   GUDID Unlock Functionality Overview:

- GUDID Coordinator user can unlock device records for editing via the GUDID Web Interface.
- Any Published DI record that has passed grace period (i.e., after-grace-period) can be unlocked.
- A single record or multiple records may be unlocked at any given time.
- The record will remain unlocked for 5 calendar days (starting the day after the record is unlocked) to submit edits.
- Once unlocked, all data elements except the DI Record Publish Date may be edited.
- Edits for unlocked records can be submitted either via the GUDID Web Interface (by the GUDID Labeler Data Entry (LDE) user) or the GUDID HL7 SPL submission option
- Records will be locked upon successful processing of the submitted edits (or after completion of the 5 calendar day unlock period, whichever is earlier).
- Updated information will be released to public users on AccessGUDID and OpenFDA on the next scheduled release date.
- All prior published versions of a given record will remain accessible on AccessGUDID and OpenFDA as device record history

Note: Please do NOT use unlock functionality to submit edits to DI records if the changes require assignment of a new Device Identifier. Refer to the GUDID Data Elements Reference Table, New DI Trigger column.

2. Unlocking Device Records via the GUDID Web Interface

Log in into the GUDID Web Interface as a Coordinator[4] user.
Click the **Manage DI** tile or **Manage DI** from the menu bar. See below.

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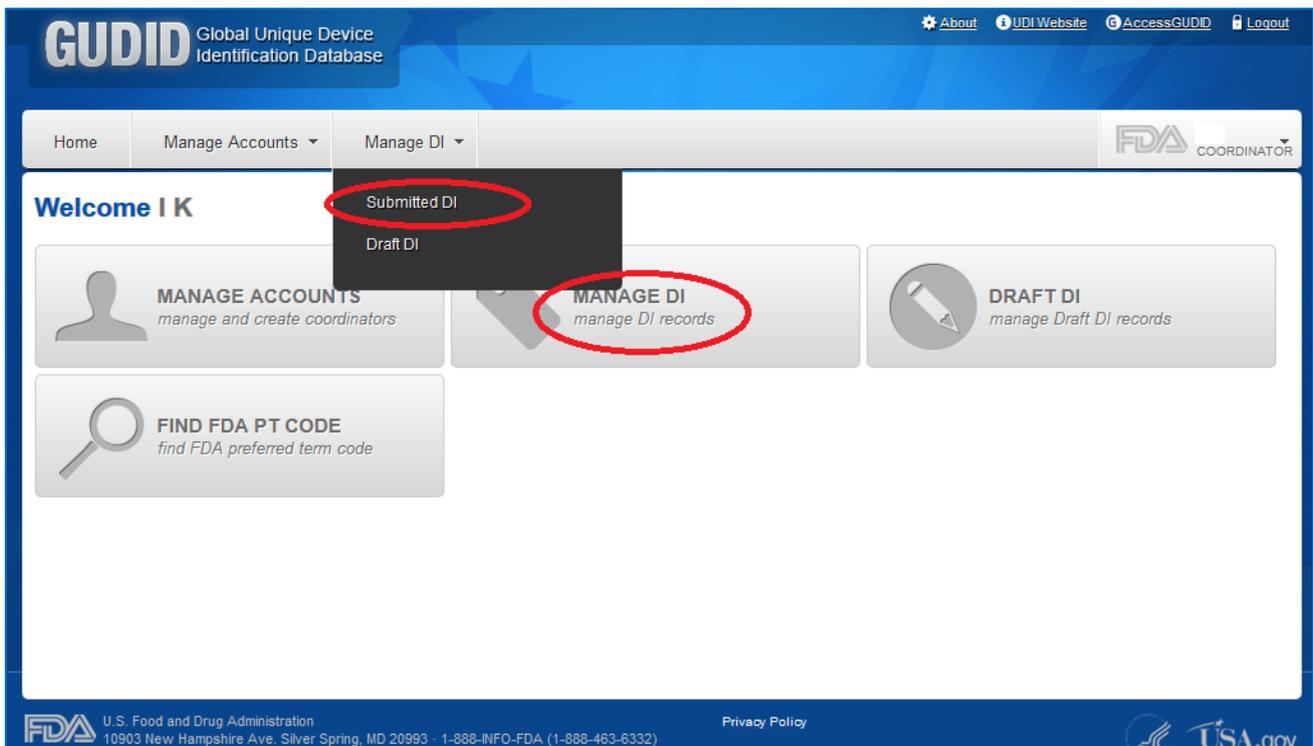
[4] For more information on GUDID user roles and functions, please refer to the GUDID User Manual.

On the **Manage Device** page, you will view your Published/Unpublished/Deactivated device records as shown below.

See the newly added "Unlock" button as shown on the right side of the screen below.

To unlock records, you may filter for specific DI records via any of the fields provided – DI Number, Brand Name, Version or Model number, DI Record Status (Published/Unpublished/Deactivated), User Name, Company Name, Labeler DUNS Number, and DI Record Edit Status. Enter information into the field you desire to filter by and click **Filter**.

Tip: Selecting DI Record Status as Published and DI Record Edit Status as After Grace Period and then clicking Filter will provide all records that are eligible to be unlocked.

Select the DI records you wish to unlock by clicking the checkboxes in the leftmost column of the table.

After selecting the records for unlocking, click on the Unlock button.

A popup window will display as shown below.

Select Cancel if you DO NOT wish to begin the unlock process.

Select Confirm if you wish to continue and unlock your records.

After you click Confirm, the system will process your unlock request and provide a popup with a summary of the process.

Unlock Device Record(s)

UNLOCK REQUEST SUMMARY

Your unlock request has been processed.
Successful Unlock(s): 2
Failed Unlock(s): 0
    Possible reasons for unlock failure:
        Unpublished DI record – all fields are editable
        Published DI record in Grace Period – all fields except DI Record Publish Date are editable
        Deactivated DI record
        Unlocked DI record

[Close]

An automated system generated email will be sent to the Coordinator user who initiated the Unlock process. See below:

Food and Drug Administration
Global Unique Device Identification Database

Dear Test1 Coordinator,

This email is to notify you that on Mar 28, 2018 12:26:04 PM you requested to unlock the following Primary Device Identifier(s) for editing.
Please note that Unlocking should ONLY be used to correct data submission errors. DO NOT USE UNLOCK TO SUBMIT EDITS THAT REQUIRE ASSIGNMENT OF A NEW DEVICE IDENTIFIER. You need to assign a new Device Identifier and submit a new record if you are changing data elements that are "New DI Triggers" (i.e., not correcting submission errors).

GUDID Account Labeler Organization DUNS Number: 162773790
Labeler Organization Name: Safeway Inc.
Total Unlock Requested: 2

Successful Unlock(s): 2

Labeler DUNS Number	Primary Device Identifier
362157088	NEEDTOTEST
362157088	IRKTEST1

You have until 04/02/2018 to update all data elements except for the DI Record Publish Date, which cannot be changed.

Failed Unlock(s): 1
82544454890404

Possible reasons for unlock failure maybe that the DI record is a(an):
Unpublished DI record - all fields are editable
Published DI record in Grace Period - all fields except DI Record Publish Date are editable
Deactivated DI record
Unlocked DI record

To access the GUDID, select the link below (or copy and paste the URL into your browser) and enter your user name and password to sign in: https://gudid.preprod.fda.gov/gudid.

Please do not reply to this e-mail as it is automatically generated.
If you have questions or comments, please visit http://www.fda.gov/udi and click on the 'FDA UDI Help-Desk' link to contact us.

Thank You,
FDA UDI Team

Your selected records have now been unlocked for editing.

The DI Record Edit Status for unlocked records will be shown as "Unlocked"

You may view, print or export records for review.

You can update and resubmit your records immediately after unlocking them. You will have 5 calendar days, starting from the day after a record is unlocked, to complete your updates and submit. After 5 calendar days, if a record has not been updated and resubmitted, it will be automatically relocked by the system.

The following type of records may not be unlocked. If a user attempts to do so, the unlock process will fail and the system will notify the user via the Unlock Request Summary popup and system generated email.

- Draft DI record
- Unpublished DI record
- Deactivated DI record
- Published DI record within grace period
- Published DI record that is already unlocked

3. Editing Unlocked Device Records

Unlocked records may be edited via the GUDID Web Interface or via the GUDID HL7 SPL submission option.

GUDID Web Interface Edits – A GUDID Labeler Data Entry (LDE) User[5] may edit and submit corrections to unlocked DI records.

GUDID HL7 SPL submission edits -- To submit edits to unlocked DI records via the GUDID HL7 SPL submission option, follow existing edit and versioning rules as specified in the GUDID HL7 SPL Implementation Files. Records that are maintained via web data entry may not be updated via HL7 SPL due to a web record's lack of HL7 SPL specific elements such as the document.id, set.id and version number. Refer to Section 3.5 Versioning of the GUDID HL7 SPL Implementation Guide for more information.

After a record is edited and resubmitted, the system will relock the record and reset its DI Record Edit Status to 'After Grace Period'. Updates will be sent to AccessGUDID and OpenFDA on the next scheduled release date.

Tip: Updates made to unlocked records should be reviewed prior to submission. Records will be locked immediately and updates will be sent to AccessGUDID on the next scheduled release.

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[5] For more information on GUDID user roles and functions, please refer to the GUDID User Manual.

A record that is unlocked and not updated will be locked after 5 calendar days, and its DI Record Edit Status will be set to 'After Grace Period'. The record may be unlocked again if necessary; however, we suggest you initiate unlock once you are ready to make the updates in GUDID.

Please note that the history of all edits is maintained and will be made available on AccessGUDID.

Additional Resources

[FDA UDI Rule](#)

[GUDID Guidance Document](#)

[GUDID User Manual](#)

[GUDID Data Elements Reference Table](#)

[HL7 SPL Implementation Package of Files](#)