GUDID: Access to Standard Device Information

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Unique Device Identification System

- 2007 FDAAA – the system
- 2012 FDASIA – the timelines
- 2013 Final Rule

CDRH Learn Unique Device Identification (UDI) System – The Final Regulation  [www.fda.gov/CDRHLearn](http://www.fda.gov/CDRHLearn)

CDRH Device Advice–UDI  [www.fda.gov/udi](http://www.fda.gov/udi)
Establishing the UDI System

- Develop a standardized system to create the UDI
- Implement UDI labeling requirements
- Create and maintain the Global UDI Database
- Adoption and Implementation by all stakeholders
<table>
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<tr>
<th>Compliance Date</th>
<th>Must bear a UDI &amp; submit data to GUDID</th>
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| September 24, 2014      | • Class III devices, including class III stand-alone software  
                          • Devices licensed under the PHS Act |
| September 24, 2015      | • Implantable, life-supporting and life-sustaining (I/LS/LS) devices, including stand-alone software  
                          • Direct Marking of LS/LS devices, for certain intended uses |
| September 24, 2016      | • Class II devices  
                          • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses |
| September 24, 2018      | • Class I devices and devices not classified as class I, II or III  
                          • Direct Marking of class II devices for certain intended uses |
| September 24, 2020      | • Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses |
UDI = Unique Device Identifier

- **DI** = mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device

- **PI** = a conditional, variable portion of a UDI that identifies one or more of the following when included on the label:
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date
  - For an HCT/P regulated as a device, the distinct identification code
Repository of key device identification information

Contains ONLY the DI; PIs are **not** submitted to or stored in the GUDID

- Contains only PI flags to indicate which PI attribute(s) are on the device label
Device Identifier Record

DI Record = Device Identifier (DI) + GUDID attributes

CompuHyper GlobalMed®

Unique Medical Device

Brand Name

GMDN Description

Device Count

Production Identifier: Expiration Date

Storage and Handling

Size: 20mm x 12.5mm

Qty: 1 each

REF Z4321

Size

Catalog Number

Unique Device Identifier (DI & PI)

Production Identifier: Serial Number

Production Identifier: Lot Number

For Single Use

Manufacturer

CompuHyper GlobalMed, LTD
101 Innovation Drive,
New Sales, MD 20999-0000

Labeler Name & Physical Address

Customer Contact Information

FDA/CDRH/OSB/Informatics Staff
GUDID Overview

Labelers - GUDID Submission Options

GUDID HL7 SPL Submission

GUDID Web Interface

FDA Electronic Submissions Gateway

Future

Public Users - GUDID Search & Retrieval Options

Public Users

Global Unique Device Identification Database

FDA: CDRH: OSB: Informatics Staff
• Working with National Library of Medicine (NLM) to provide public “Access” to GUDID
  o GUDID public search
  o GUDID download files
  o GUDID web services -- future

• Expected release – Spring 2015
SEARCH RESULTS FOR: wsdioverview (1 results)

Did you mean dioverview?

**DIOverview - wsdIOverview**

DIOverviewRecord

**Company Name:** Safeway Grocery

**Model Number:** 123456

**GMDN Terms:**

- FOR TESTING PURPOSES ONLY

**Device IDs:**

- wsPkg2 (Package)
- wsPkg1 (Package)
- wsdIOverview (Primary)
- 00909090909090 (Secondary)

**Device Sizes:**

- Length: 3.56789999000 Femtometer
- Depth: 2.5 Centimeter
DOWNLOAD GUDID DATA

GUDID data downloads may be most useful for hospitals and other health care systems, researchers, registries, and third-party data aggregators providing GUDID data to users in "real time". This page contains the latest full database releases files.

If you need help downloading the GUDID data or understanding the GUDID file schema, please visit the Download Section of the Help Page.

DAILY RELEASES

• gudid_daily_update_20150209.zip
  Date Created: Feb 09, 2015  Number of Device Identifier Records: 4606  File Size: 186 KB
  MD5 Checksum: 3ecc0ae5bcca4d894965f52fd710ae3

WEEKLY RELEASES

No Files Found

LATEST FULL RELEASE

• gudid_full_release_20150206.zip
  Date Created: Feb 06, 2015  Number of Device Identifier Records: 43429  File Size: 2.68 MB
  MD5 Checksum: 65b566f8c3a4c6fac5c1e9fe1da071fe
For more information, please visit: www.fda.gov/udi