

UDI for Patient Safety and Transformation

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Unique Device Identifier (UDI)

The key to “unlock”
device information



Learning Objectives

- Explain the UDI Rule requirements
- Describe current UDI Program Status
- Discuss UDI Adoption and Implementation Activities

UDI Rule Requirements



September 24, 2013: UDI Final Rule Published

Establish a system to adequately identify devices through distribution and use



Device label, device
package &
sometimes device
itself must bear UDI



Device identification
data must be
submitted to the
GUDID

Key Rule Requirements

FDA UDI Program Objectives

Establish a system to adequately identify devices through distribution and use

- Facilitate rapid and accurate identification of a device
- Provide a standard way to document device use in real world data sources
- Allow for more accurate reporting, reviewing, and analyzing of adverse event reports
- Enable more effective management of medical device recalls

What is a UDI?

Required on the device label, packaging and, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

UDI = DI + PI

DI = device identifier
PI = production identifier

Qty: 1 each Size: 20mm x 12.5mm **REF** Z1234

(01)12345678901234 (17)140102(11)100102(10)A1234(21)1234

2014-01-02
 2010-01-02
 LOT A1234
 SN 1234

45°C
UPPER LIMIT OF TEMPERATURE

KEEP DRY

Manufacturer

CompuHyper GlobalMed, LTD

101 Innovation Drive,
New Sales, MD 20999-0000

XXX-867-5309 (USA)
XXX-555-3226 (Outside USA)
<http://www.compuhypergm.com>



“Good-ID”

Repository of key device identification information

Data in GUDID should match data on medical device labeling

Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID

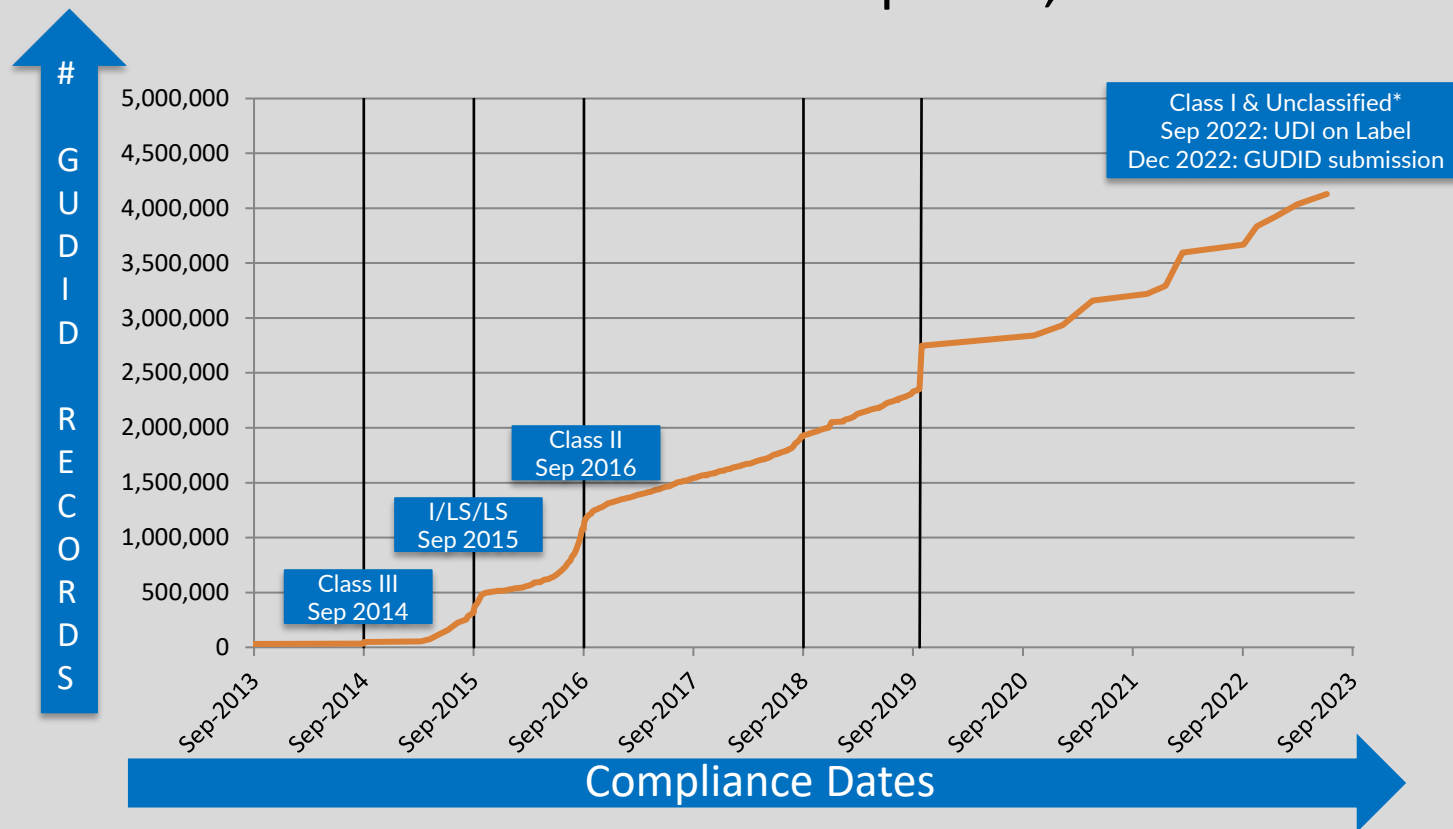
Contains only PI flags to indicate which PIs are on the device UDI

- New Version or Model requires new UDI-DI, and a new record in GUDID
 - Under [21 CFR 801.3](#), version or model means *all devices that have specifications, performance, size and composition, within limits set by the labeler*.
- 21 CFR 830.330 (b) requires that when submitted information changes, GUDID be updated.
 - Obsolete GMDN Codes
 - Commercial Distribution End Date
 - Customer Contact Information

UDI Program: Current Status

Global Unique Device Identification Database: “Good-ID”

>4.3 million records as of April 30, 2024



*September 24, 2018: UDI Rule Compliance Date,
September 24, 2022 & Dec 8, 2022: Compliance policy regarding enforcement via guidance

UDI for Soft Contact Lens

- Time extension [UDI-E140001](#) in place

Device Class	Device	Product Code
Class III	Soft (hydrophilic) Contact Lens (extended wear)	LPM
Class II	Soft (hydrophilic) Contact Lens (for color vision deficiency)	NCZ
	Soft (hydrophilic) Contact Lens (for reading discomfort)	NIC
	Soft (hydrophilic) Contact Lens (daily wear)	LPL
	Soft (hydrophilic) Contact Lens (disposable)	MVN

- Working on potential solution options

ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE



ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S. from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. AccessGUDID also offers RSS feeds and APIs to connect you directly to the data.

[MORE INFO](#)

[ABOUT UDI](#)

[ABOUT GUDID](#)

DOWNLOAD

[Download Data](#)



Download the latest full releases and update files provided to the NLM by the FDA.

API

[API Documentation](#)



Resources for application developers to get the most out of AccessGUDID.

RSS

[RSS Documentation](#)



Subscribe to RSS feeds to receive the latest files.



AccessGUIDID

accessguidid.nlm.nih.gov/

[VIEW ALL SECTIONS](#) | [CLOSE ALL SECTIONS](#)

− DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: MITRACLIP
Version or Model: CDS0701-XTW
Commercial Distribution Status: In Commercial Distribution
Catalog Number: CDS0701-XTW
Company Name: ABBOTT VASCULAR INC.
Device Description: MitraClip G4 Clip Delivery System XTW

Primary DI Number: 08717648231001
Issuing Agency: GS1
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 964569052 [*Terms of Use](#)

[CLOSE](#)

+ DEVICE CHARACTERISTICS

+ DEVICE RECORD STATUS

+ ALTERNATIVE AND ADDITIONAL IDENTIFIERS

+ CUSTOMER CONTACT [?]

− DEVICE CHARACTERISTICS

<u>What MRI safety information does the labeling contain?</u>	MR Conditional
<u>Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):</u>	No
<u>Device labeled as "Not made with natural rubber latex":</u>	No
<u>For Single-Use:</u>	Yes
<u>Prescription Use (Rx):</u>	Yes
<u>Over the Counter (OTC):</u>	No
<u>Kit:</u>	No
<u>Combination Product:</u>	No
<u>Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):</u>	No

+ GMDN [?]

+ FDA PRODUCT CODE [?]

+ FDA PREMARKET SUBMISSION

+ STERILIZATION

+ STORAGE AND HANDLING [?]

+ CLINICALLY RELEVANT SIZE [?]

+ DEVICE RECORD STATUS

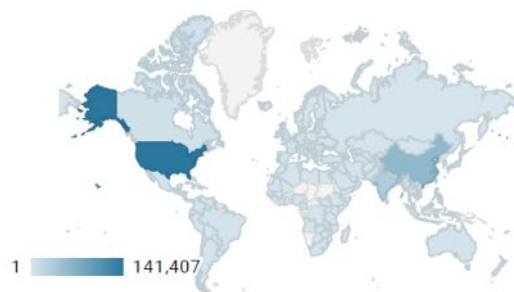
+ ALTERNATIVE AND ADDITIONAL IDENTIFIERS

+ CUSTOMER CONTACT [?]

Usage Data for April 2024

Users	Sessions	Pageviews	Homepage Pageviews	Avg. Sessions per Day
116,954	263,498	1,555,064	96,478	8,783.27
↑ 29.4%	↑ 15.8%	↑ 7.2%	↑ 3.5%	↑ 19.7%

Location



	Country	Sessions ▾
1.	United States	130.7K
2.	India	28.7K
3.	Philippines	4.2K
4.	Canada	3.6K
5.	China	2.2K
6.	Germany	2K
7.	United Kingdom	1.7K
8.	Mexico	1.2K
9.	Japan	982
10.	Vietnam	833

United States
Sessions

141.4K

↑ 6.0%

International
Sessions

122.1K

↑ 29.6%

United States
Pageviews

902.4K

International
Pageviews

652.6K



Download and API Usage

April 2024

How many HTTP files were downloaded last month?

Total Events

2,286

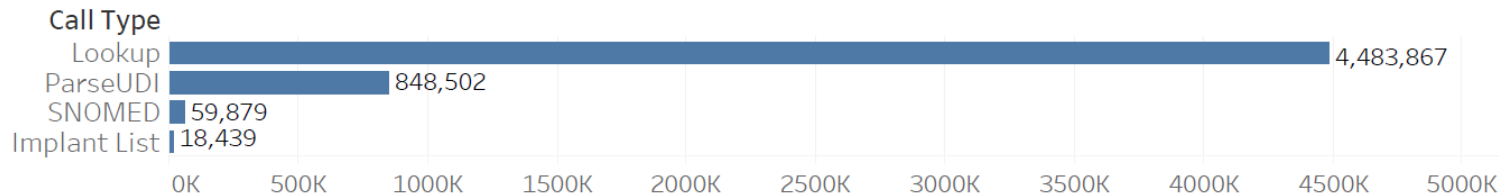
↓ -10.1%

Unique Events

1,914

↓ -14.8%

API Request Analysis (Last month, Log data)



API = application programming interface



510(k) clearances

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device.

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Classification

Medical device names, their associated product codes, their medical specialty areas (panels) and their classification.

[LEARN MORE >](#)



Recall enforcement reports

Medical device product recall enforcement reports.

[LEARN MORE >](#)



Adverse event reports

Reports of serious injuries, deaths, malfunctions, and other undesirable effects associated with the use of medical devices.

[LEARN MORE >](#)



Premarket approval

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

[LEARN MORE >](#)



Recalls

A recall is an action taken to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

[LEARN MORE >](#)



Registrations and listings

The registration and listing dataset contains the location of medical device establishments and the devices manufactured at those establishments.

[LEARN MORE >](#)



Unique device identifier

Global Unique Device Identification Database (GUDID) Device Identification dataset.

[LEARN MORE >](#)



COVID-19 serological testing evaluations

Serology tests detect the presence of antibodies in the blood when the body is responding to a specific infection, like COVID-19.

[LEARN MORE >](#)

Knowledge Check

Which of these does the UDI-DI identify

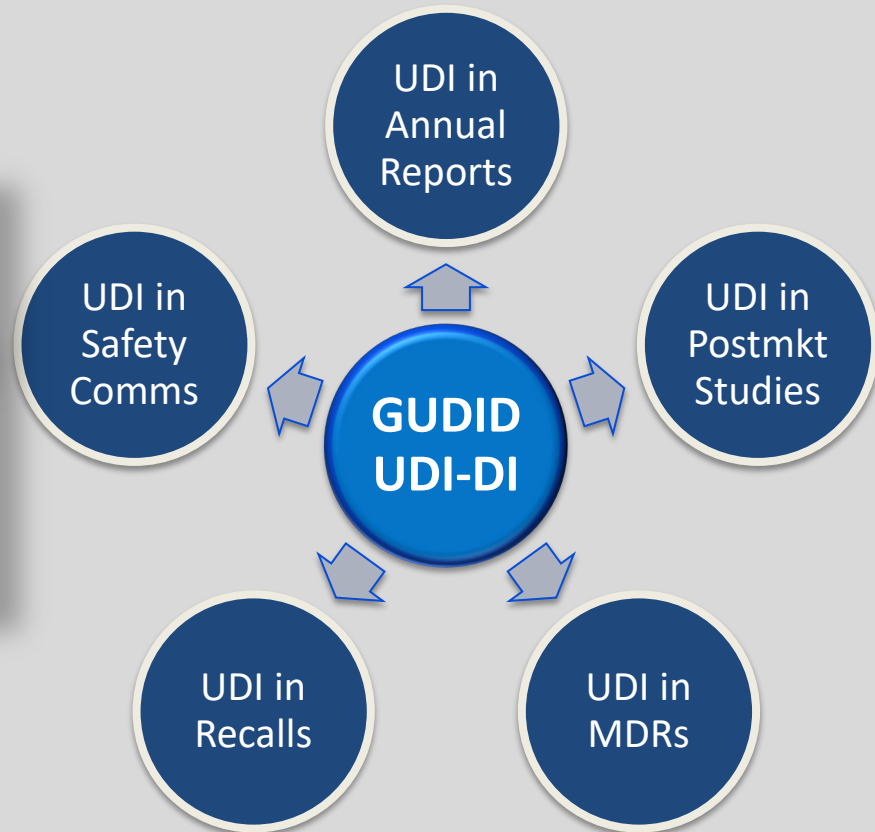
- 1. Device finger-print**
- 2. Device version or model**
- 3. Device version or model and labeler of device**
- 4. Device production data (such as, lot or batch, serial number, expiration or manufacturing date)**



UDI Adoption and Implementation

GUDID: Device Identification Source

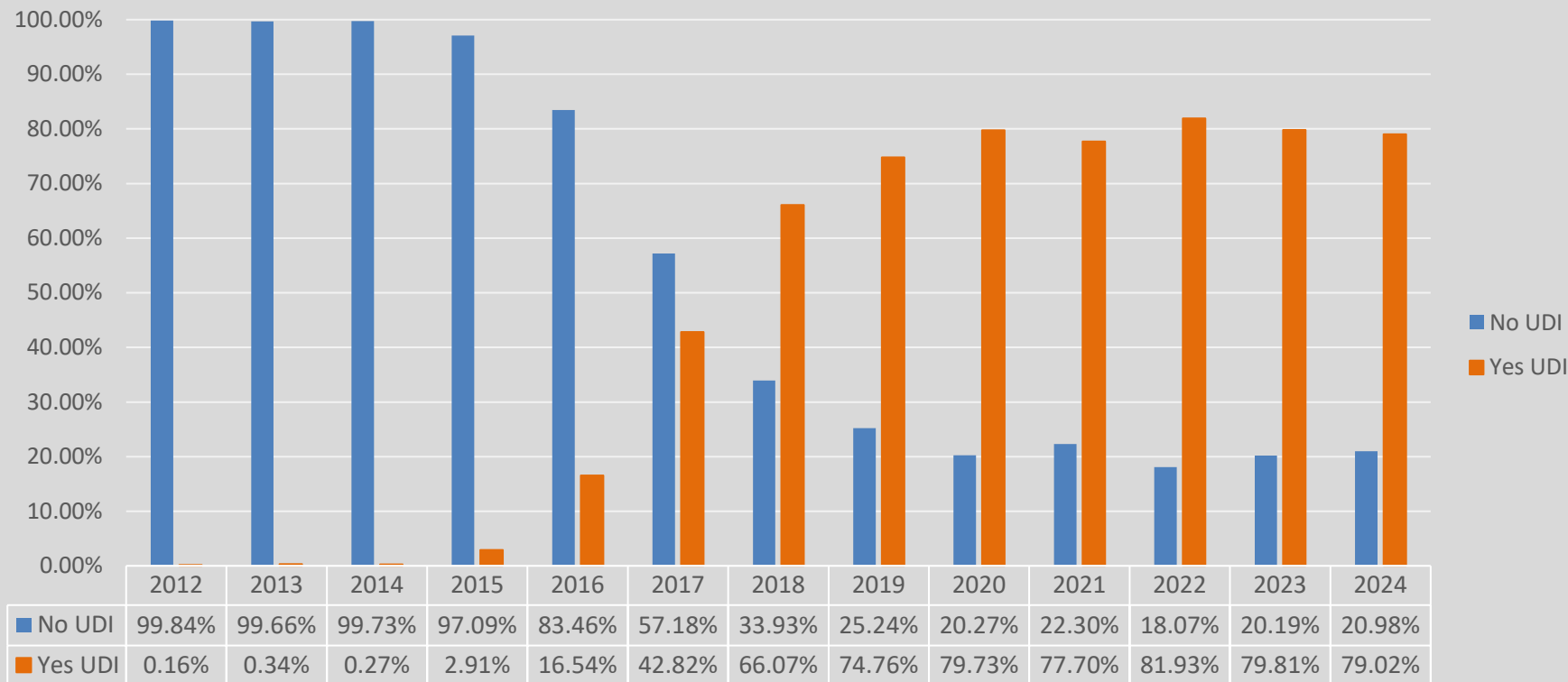
Device identification data submitted to CDRH should match data in GUDID



% Device Adverse Events with UDIs: CY2012-24*



Ability to aggregate adverse events using UDI-DI



*Data as of March 31, 2024

UDI for Safety Signal Detection

Medwatch Forms



D. SUSPECT MEDICAL DEVICE	
1. Brand Name	
2a. Common Device Name	
3. Manufacturer Name, City and State	
4. Model #	Lot #
Catalog #	Expiration Date (dd-mmm-yyyy)
Serial #	Unique Identifier (UDI) #

Please include the *full UDI* including all parentheses and symbols on 3500 forms

Available Now: MDR search by UDI-DIs

MAUDE - Manufacturer and User Facility Device Experience Database

Search Database

 Help
  Download Files

Product Problem

Product Class

Event Type

Manufacturer

Model Number

Report Number

Brand Name

Product Code

Summary Report

Exemption Number

UDI-Device Identifier

05415067020222

Date Report Received by FDA (mm/dd/yyyy)

04/01/2024

to

04/30/2024

PMA/510K Number

[Go to Simple Search](#)

10

Records per Report Page

Clear Form

Search

Brand Name

PROCLAIM₂ 7 ELITE IMPLANTABLE PULSE GENERATOR

Type of Device

SCS IPG

Manufacturer (Section D)

ABBOTT MEDICAL
6901 Preston Rd
Plano TX 75024

Manufacturer (Section G)

ABBOTT MEDICAL
6901 Preston Rd
Plano TX 75024

Manufacturer Contact

Heidi Syndergaard
6901 Preston Road
Plano, TX 75024
9723098000

MDR Report Key

19210276

MDR Text Key

341356880

Report Number

1627487-2024-08444

Device Sequence Number

1

Product Code

LGW

UDI-Device Identifier

05415067020222

UDI-Public

(01)05415067020222(10)6307446(17)200212

Implant Device



FDA Term for Our Analysis	GEN 1	GEN 2	GEN 3
Marketed Brand Name	Device A		Device A1
Graft Material	Material A	Material B	
PMA Supplement Number	15	25	35
Safety Signal	Class I recall in 2018	Uncertain*	
Product Lifetime	2011-2016	2014-2020	2016-Present

Revealing previously hidden GEN 2 Dataset w/ UDI

- Looking at Brand name only limited our review
- UDI allowed reveal of **GEN 2** data previously reported by **GEN 1 Brand Name**

Total Dataset

No UDI

w/
UDI

Brand
Name

**GEN 1
Brand
Name**

GEN 3
Brand
Name

w/ UDI

GEN
1 UDI

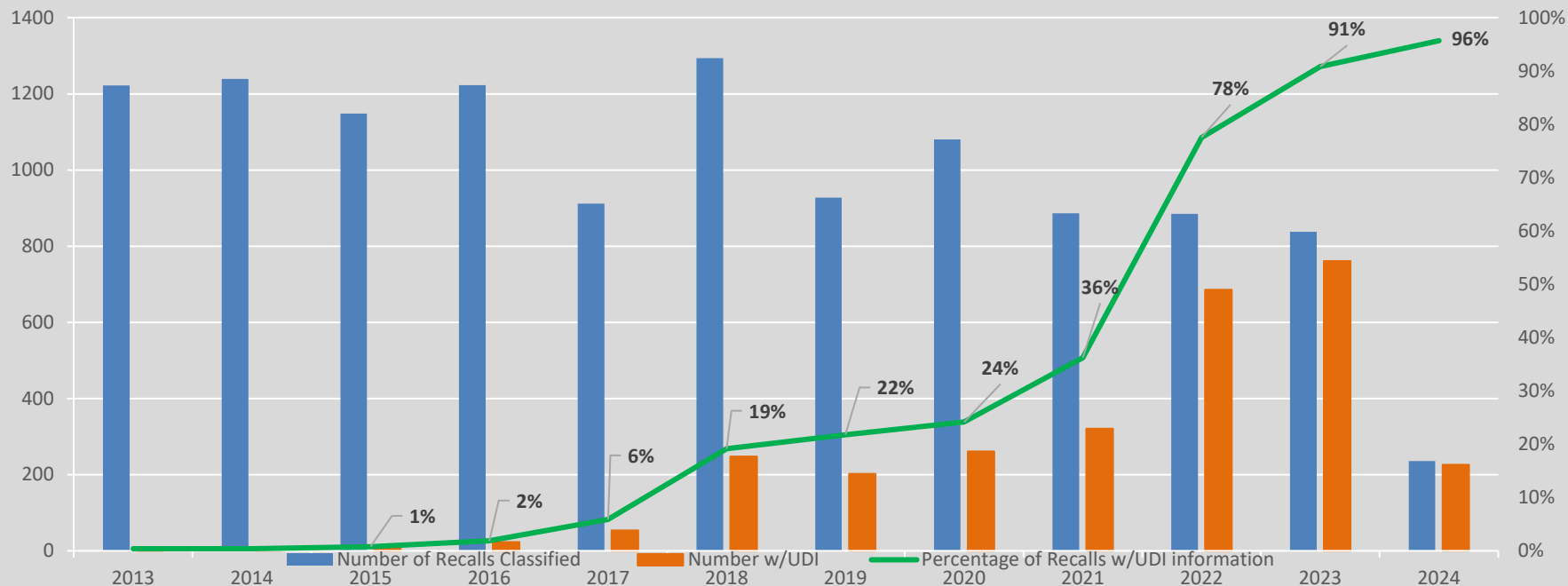
**GEN 2
UDI**

GEN 3
UDI

Over 1/3 recategorized with use of UDI

	Adverse Events Using Brand Name	Adverse Events using UDI	Adverse Events recategorized (%)
GEN 1	1,809	1,440	-369 (20.4%)
GEN 2	0	365	+365 (100.00%)
GEN 3	262	266	+4 (1.50%)
Total MDR	2,071		738 (35.63%)

% Medical Device Recalls with UDIs CY2013-24*



*Data as of April 30, 2024

UDI in Recalls

Helps quickly identify and remove recalled devices from inventory

Public Release of UDIs in Recalls Database

Medical Device Recalls
[FDA Home](#) [Medical Devices](#) [Databases](#)

This database:

- contains Medical Device Recalls classified since November 1, 2002.

[Learn More...](#)

[Advanced Search](#)

Product Classification	Microscope and microscope accessories, reproduction, assisted -
Product Code	MTX
Product Code Information	Brand X microscope
	UDI-DI: 4060000754897

- Please include complete UDI information as part of your recall submissions to FDA
- Include UDI in recall notices to customers
- Post UDI information on your recall information web pages and link to GUDID DI record

UDI in Safety-Related Communications

- Inclusion of UDI in CDRH issued device safety-related communications
 - [Hintermann Series H3 Total Ankle Replacement Has a Higher-Than-Expected Risk of Device Failure: FDA Safety Communication](#)
 - [BioZorb Markers and Potential Risks with Use in Breast Tissue: FDA Safety Communication](#)

Please include UDIs in all YOUR safety related communications also!

- on your website
- direct customer notifications

Provide links to GUDID DI records

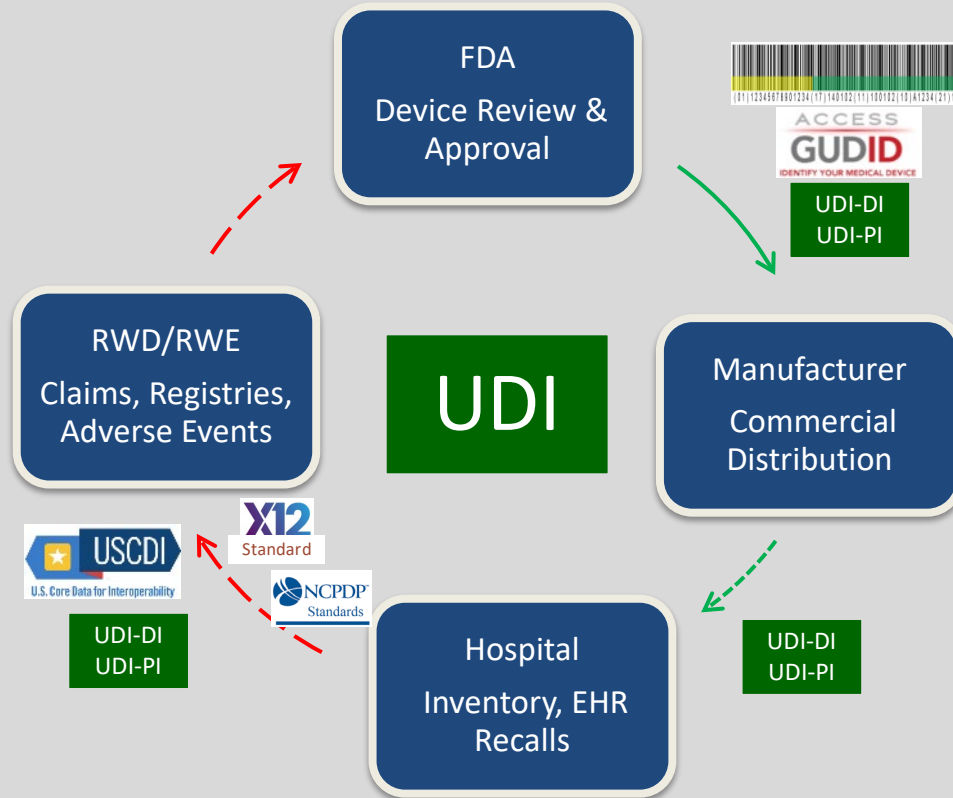
Version or Model	Device Brand Name	Device Description	Device Identifier (DI) Number
F0405	BioZorb Bioadsorbable Marker	BioZorb Marker 4cm x 5cm	15420045514065
F0404	BioZorb Bioadsorbable Marker	BioZorb Marker 4cm x 4cm	15420045514058
F0304	BioZorb Bioadsorbable Marker	BioZorb Marker 3cm x 4cm	15420045514010
F0303	BioZorb Bioadsorbable Marker	BioZorb Marker 3cm x 3cm	15420045514003
F0203	BioZorb Bioadsorbable Marker	BioZorb Marker 2cm x 3cm	15420045513990
F0202	BioZorb Bioadsorbable Marker	BioZorb Marker 2cm x 2cm	15420045513983
F0331	BioZorb LP Bioadsorbable Marker	BioZorb Marker 1cm x 3cm x 3cm	15420045514041
F0231	BioZorb LP Bioadsorbable Marker	BioZorb Marker 1cm x 3cm x 2cm	15420045514034
F0221	BioZorb LP Bioadsorbable Marker	BioZorb Marker 1cm x 3cm x 2cm	15420045514027

UDI Compliance

- Ensuring UDI rule requirements are implemented correctly
 - Properly formed UDI on device labels and packages
 - Completeness and quality of data submission to GUDID
 - All active listings have an associated DI record in GUDID if UDI requirements apply
 - Data Quality of UDI submitted in MDRs and Recalls
- UDI included as part of routine inspections
 - 2023: 4 Warning Letters with UDI/GUDID charges
- UDI review during imports label screening nation wide

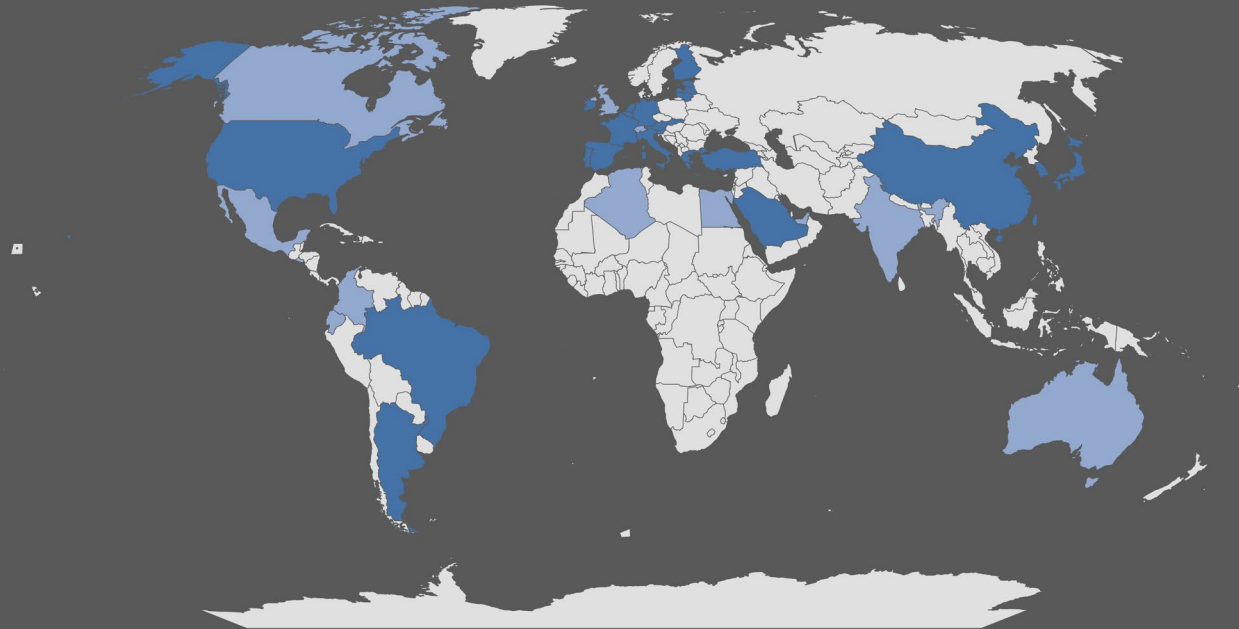
MDR = medical device reporting

UDI Adoption Vision



Global UDI Landscape

■ Current Regulation ■ Reg Under Development



Current UDI Regulation

- USA
- EU
- China
- South Korea
- Turkey
- Saudi Arabia
- Taiwan
- Brazil
- Singapore
- Japan
- Argentina

UDI Reg Under Development

- India
- Ecuador
- Australia
- UK
- Columbia
- Algeria
- Egypt
- Canada
- El Salvador
- Switzerland
- Mexico
- UAE

Knowledge Check

MagicalDevice Company sells “BackAcheGoAway” device that cures back aches magically. Models 1 and 2 are on the market; Model 3 is ready to launch. The company no longer plans to sell Model 1.

Should they update their GUDID?

- a. No. GUDID data already exists for Model 1
- b. Yes. To update Model 1 record to enter “Commercial Distribution End Date.” Status will show “No Longer in Commercial Distribution”
- c. Yes. To enter a new record for Model 3
- d. Both b and c

Summary

- Two key requirements of the UDI Final Rule:
 1. Device label, device package and sometimes device itself must bear UDI
 2. Device identification data must be submitted to the Global Unique Device Identification Database (GUDID)
- UDI compliance focus: ensuring UDI requirements are implemented correctly
- UDI adoption and implementation activities support patient safety and transformation

Resources



Slide Number	Cited Resource	URL
9	21 CFR 801.3	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801/subpart-A/section-801.3
12	UDI-E140001	www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-exceptions-and-alternatives
14	AccessGUDID	accessgudid.nlm.nih.gov/about-gudid
23	MAUDE - Manufacturer and User Facility Device Experience	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
28	Microscope and microscope accessories, reproduction, assisted	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MTX
28	MTX	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MTX

Resources



Slide Number	Cited Resource	URL
29	Hintermann Series H3 Total Ankle Replacement Has a Higher-Than-Expected Risk of Device Failure: FDA Safety Communication	www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety
29	BioZorb Markers and Potential Risks with Use in Breast Tissue: FDA Safety Communication	www.fda.gov/medical-devices/safety-communications/biozorb-markers-and-potential-risks-use-breast-tissue-fda-safety-communication
29	2024 Safety Communications	www.fda.gov/medical-devices/safety-communications/2024-safety-communications

Other UDI Resources



Resource	URL
FDA UDI Website	www.fda.gov/udi
CDRH Learn Website	www.fda.gov/training-and-continuing-education/cdrh-learn#collapseFour
FDA UDI Help Desk	fda-cdrh.my.salesforce-sites.com/UdiWebForm
Public Access to GUDID Data: Access GUDID	accessgudid.nlm.nih.gov/
Public Access to GUDID Data: Open FDA	open.fda.gov/apis/device/udi/

Questions




Your Call to Action

- Meet the intent of the UDI Rule
- Ensure your data in GUDID are complete, accurate, usable and helpful to patients and healthcare providers
- Populate optional data critical for adoption
 - Catalog Number
 - Customer Contact
 - Full and complete “Device Description”
 - Commercial Distribution End Date

Your Call to Action

- Use the UDI Symbol (ISO-15223-1:2021) on device labels to aid in identification of the UDI

<p>5.7.10</p> 	<p>Unique device identifier</p>	<p>Indicates a carrier that contains unique device identifier information</p>	<p>This <i>symbol</i> may be used when multiple data carriers are present on the label. If used, this <i>symbol</i> shall be placed adjacent to the unique device identifier carrier.</p>
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