



AccessGUDID, Are You There Yet & Why You Should Be?

Understanding UDI & the latest deadlines.

CDR Stephen Smith, CSO - June 2021

Goals

- UDI History & Current guidance
- Extensions to some timelines
- Sources/Links for UDI info
- What to expect from the inspection process...

Establishing a UDI System

UDI Final Rule

[78 FR 58786]

Sept 24, 2013

Develop a standardized system to create the UDI

Place UDI on label and (sometimes) the device

Create and maintain the Global UDI Database

Adoption and Implementation



Why make this system?

- To offer a range of benefits to industry, FDA, consumers, health care providers and health care systems by:
- Allowing more accurate reporting, reviewing and analyzing of adverse event reports...
- Reducing medical errors by precisely identifying a device...
- Enhanced analysis of documented device use in **Electronic Health Records & Clinical Info** systems

(More can be seen on Benefits of a UDI System.)

- <https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system>

Implementation Timeframe

	Date	Must bear a UDI and Submit data to GUDiD	Direct Marking (for certain intended uses)
✓	Sep 24, 2014	Class III devices Devices licensed under the PHS Act	
✓	Sep 24, 2015	Implantable, life-supporting and life-sustaining (I/LS/LS) devices	LS/LS devices
✓	Sep 24, 2016	Class II devices (not I/LS/LS)	Class III devices and devices licensed under the PHS Act
✓	Sep 24, 2018	Class I devices Unclassified devices (not I/LS/LS)	Class II devices (not LS/LS)
✓	Sep 24, 2020	Class I devices Unclassified devices (not I/LS/LS)	Class I devices Unclassified devices (not LS/LS)
	Sep 24, 2022	Class I devices Unclassified devices (not I/LS/LS)	Class I devices Unclassified devices (not LS/LS)

2018
Guidance

2020
Guidance

2018
Guidance



Where to start?

- A **unique device identifier (UDI)** is a unique numeric or alphanumeric code that generally consists of the following:
- **Device identifier (DI)**, a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
- **Production identifier (PI)**, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
 - **Lot or batch number** within which a device was manufactured
 - **Serial number** of a specific device
 - **Expiration date** of a specific device
 - **Date** a specific device was **manufactured**;
 - **Distinct identification code required** by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

What is the UDI?



REPLACEMENT CAP, WHITE FEMALE LUER LOCK¹

100 Quantity

STERILE EO

CE 0123

2020-07-31
Expiration Date

LOT 0061443956

REF 474900

PRODUCT CODE W1000

P5000366-7
REV. 9/15



(01 04022495770332(17)200731(10)0061443956

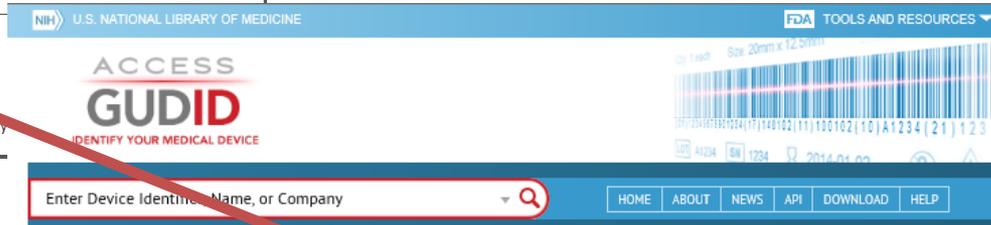
GTIN 04022495770332

B | BRAUN
B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862
www.bbraun.com

EC REF
B. Braun Melsungen AG
34209 Melsungen, Germany

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

Code in plain text and machine readable format (AIDC)



DEVICE: Replacement Cap 04022495770332

DOWNLOAD: XML | JSON PRINT

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Replacement Cap
Version or Model: 474900
Catalog Number: 474900
Company Name: B. BRAUN MEDICAL INC.
Device Description: White Replacement Cap

Primary DI Number: 04022495770332
Issuing Agency: GS1
Device Count: 100

CLOSE

- + DEVICE CHARACTERISTICS
- + DEVICE STATUS
- + ALTERNATIVE AND ADDITIONAL IDENTIFIERS
- + CUSTOMER CONTACT [2]

 =/A9999XYZ100T0479
=,000025=A99971412345600=>016008



FDA UDI's Webpage

Unique Device Identification System

Unique Device Identification System (UDI System)

UDI Basics

Benefits of a UDI System

Compliance Dates for UDI Requirements

Contact an FDA-Accredited Issuing Agency

UDI Exceptions, Alternatives and Time Extensions

UDI Rule and Guidances, Training, Resources, and Dockets

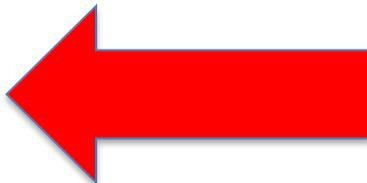
FDA UDI Help Desk

Global Unique Device Identification Database (GUDID)

News and Updates

In May 2021, the FDA issued the guidance [Enforcement Policy Regarding Use of National Health Related Item Code \(NHRIC\) and National Drug Code \(NDC\) Numbers on Device Labels and Packages](#). The guidance explains that the FDA does not intend to object to the use of legacy NHRIC and NDC numbers on device labels and device packages for finished devices that are manufactured and labeled prior to September 24, 2023.

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>



FDA Email Notifications Info from:



U.S. FOOD & DRUG ADMINISTRATION

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Content current as of: 11/06/2020

[Manage FDA Email Subscriptions](#)

Center for Devices and Radiological Health

CDRH Mission, Vision and Shared Values

Reorganization of The Center for Devices and Radiological Health

CDRH New

A daily digest of the previous business-day's new additions and updates to CDRH's webpages.

<https://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-mailing-lists>

CDRH Ombudsman

CDRH Patient Science and Engagement Program

CDRH Reports

Global UDI Database (GUDID) System Status

Provides email alerts regarding database updates and system status for the Global Unique Device Identification Database.

Email Address

[Subscribe](#)

Unique Device Identification (UDI)

Information on how the use of a Unique Device Identification (UDI) system may improve patient safety.

Email Address

[Subscribe](#)

Data Submission



Data Use

Reference device identification information
Submit once – reuse in downstream systems
Optimize data quality based upon use



AccessGUDID website (home page)

NIH U.S. NATIONAL LIBRARY OF MEDICINE FDA TOOLS AND RESOURCES

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

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](#)

NEWS
[AccessGUDID News](#)
Posted: June 28, 2019
Upcoming Changes to Public IP Addresses for AccessGUDID

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.

HELP
[Help using AccessGUDID](#)
[Searching AccessGUDID](#)
[Downloading Release Files](#)
[NLM Web Guidelines](#)



<https://accessgudid.nlm.nih.gov/>

AccessGUDID (Basic Search)

The screenshot shows the AccessGUDID website interface. At the top, there are logos for NIH U.S. NATIONAL LIBRARY OF MEDICINE and FDA TOOLS AND RESOURCES. The main header features the 'ACCESS GUDID' logo with the tagline 'IDENTIFY YOUR MEDICAL DEVICE'. Below this is a search bar with the placeholder text 'Enter Device Identifier, Name, or Company' and a magnifying glass icon. To the right of the search bar are navigation links: HOME, ABOUT, NEWS, API, DOWNLOAD, and HELP. Below the search bar is a 'Basic Search' section with a question mark icon. On the left side of this section is a vertical menu with options: Help Home, Introduction Video, Search Help, Basic Search (highlighted with a red arrow), Writing Complex Queries, Advanced Search, Search Results (highlighted with a yellow arrow), Exporting Results, and More Help. The main content area of the 'Basic Search' section has the heading 'AccessGUDID BASIC SEARCH' and a paragraph explaining that 'Basic Search' allows users to search and retrieve records based on device attributes. A bulleted list of search attributes is provided: Device Identifier (DI), Company Name, Device Brand Name, Device Common Name, and Device Version or Model. Below the list, a paragraph states that 'Basic Search' functionality can be accessed on any page of the website by typing queries into the Search Bar. It also notes that mobile users can find the Search Bar by going to the Home Page or by tapping the magnifying glass icon in the top-right corner of the website. A small inset image in the bottom right corner shows the mobile version of the website with the magnifying glass icon highlighted by a red arrow.

NIH U.S. NATIONAL LIBRARY OF MEDICINE

FDA TOOLS AND RESOURCES

ACCESS GUDID IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

HOME ABOUT NEWS API DOWNLOAD HELP

Basic Search

Help Home

Introduction Video

Search Help

Basic Search

Writing Complex Queries

Advanced Search

Search Results

Exporting Results

More Help

AccessGUDID BASIC SEARCH

Basic Search allows you to search and retrieve all records that contain the search terms you enter. Your search term must consist of at least three alphabetic or numeric characters. Basic Search allows you to search by any device attribute, such as:

- Device Identifier (DI)
- Company Name
- Device Brand Name
- Device Common Name
- Device Version or Model

Basic Search functionality can be accessed on any page of the website by typing queries into the Search Bar. Mobile users can find the Search Bar by going to the [Home Page](#) or by tapping the **magnifying glass icon** in the top-right corner of the website.

Once you fill out and submit your search query, you will be directed to the [Search Results](#) page. Basic

AccessGUDID (API's)

NIH U.S. NATIONAL LIBRARY OF MEDICINE FDA TOOLS AND RESOURCES

ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE

Q

[HOME](#) [ABOUT](#) [NEWS](#) [API](#) [DOWNLOAD](#) [HELP](#)

Resources Home

Resources Home

△ Notice

Generating UMLS Tickets

Feeds

RSS

APIs

Implantable List

Device Lookup

NOTICE

**** Update March 2020 ****
AccessGUDID V1 APIs are currently deprecated (no longer supported for bug fixes and enhancements) and will be removed after December 31, 2021.

December 28, 2018
AccessGUDID is deprecating its V1 APIs and will no longer be available for use after December 31, 2019.

The new base URL for the web service is: <https://accessgudid.nlm.nih.gov/api/v2/>

The V2 APIs are in production as of January 1, 2019.

If you are using our V1 web services, please update your code to use V2 by **January 1, 2019**. After that date, V1 APIs will no longer be supported in terms of bug fixes and enhancements. If you have questions about the switch to V2, please ask us via the [NLM Support Center](#).

What to expect from the inspection process...

- Review of new products, and products that have been updated with changes to labeling that should have been submitted to FDA
- 21 CFR 801 – Labeling, points to part 830 and Part 830.330 identifies “Times for Submission of Unique Device Identification”
- Verification of meeting those timelines for product in distribution

Part 830 Unique Device ID

[New Search](#)

[Help](#) | [More About 21CFR](#)

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES
PART 830 UNIQUE DEVICE IDENTIFICATION

Subpart A - General Provisions

[§ 830.3](#) - Definitions.

Subpart B - Requirements for a Unique Device Identifier

[§ 830.10](#) - Incorporation by reference.

[§ 830.20](#) - Requirements for a unique device identifier.

[§ 830.40](#) - Use and discontinuation of a device identifier.

[§ 830.50](#) - Changes that require use of a new device identifier.

[§ 830.60](#) - Relabeling of a device that is required to bear a unique device identifier.

Subpart C - FDA Accreditation of an Issuing Agency

[§ 830.100](#) - FDA accreditation of an issuing agency.

[§ 830.110](#) - Application for accreditation as an issuing agency.

[§ 830.120](#) - Responsibilities of an FDA-accredited issuing agency.

[§ 830.130](#) - Suspension or revocation of the accreditation of an issuing agency.

Subpart D - FDA as an Issuing Agency

[§ 830.200](#) - When FDA will act as an issuing agency.

[§ 830.210](#) - Eligibility for use of FDA as an issuing agency.

[§ 830.220](#) - Termination of FDA service as an issuing agency.

Subpart E - Global Unique Device Identification Database

[§ 830.300](#) - Devices subject to device identification data submission requirements.

[§ 830.310](#) - Information required for unique device identification.

[§ 830.320](#) - Submission of unique device identification information.

[§ 830.330](#) - Times for submission of unique device identification information.

[§ 830.340](#) - Voluntary submission of ancillary device identification information.

[§ 830.350](#) - Correction of information submitted to the Global Unique Device Identification Database.

[§ 830.360](#) - Records to be maintained by the labeler.



Authority: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

Source: 78 FR 58823, Sept. 24, 2013, unless otherwise noted.

Part 830.330 - Times for Submission of UDI

New Search

Help | More About 21CFR

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2020]
[CITE: 21CFR830.330]



TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 830 -- UNIQUE DEVICE IDENTIFICATION

Subpart E - Global Unique Device Identification Database

Sec. 830.330 Times for submission of unique device identification information.

(a) The labeler shall submit to FDA the information required by § 830.310 no later than the date the label of the device must bear a unique device identifier under § 801.20 of this chapter.

(b) The labeler of a device shall submit to FDA an update to the information required by § 830.310 whenever the information changes. The updated information must be submitted no later than the date a device is first labeled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change.



Transfer essential device information to other Health Systems



REF
1120434

Wisp Magnetic Headgear Clips, RP

LOT 160520
Made in China

GS1-128

(01) 00606959039698(10)160520

Manufactured for:
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA

Respironics Deutschland
Gewerbestrasse 17
82211 Herrsching, Germany

EC REP

CE

15

95

-20°C

+140°F

+30°C

-4°F

UDI-DI
and
UDI-PI

Medical record

John Habbits

Service

Laboratory

Schedule

Patients

2552. Larkins

2553. Lawman

2554. Leapman

2555. MacAdam

2556. MacAlister

2557. MacDonald

2558. Macduff

2559. Macey

Family history

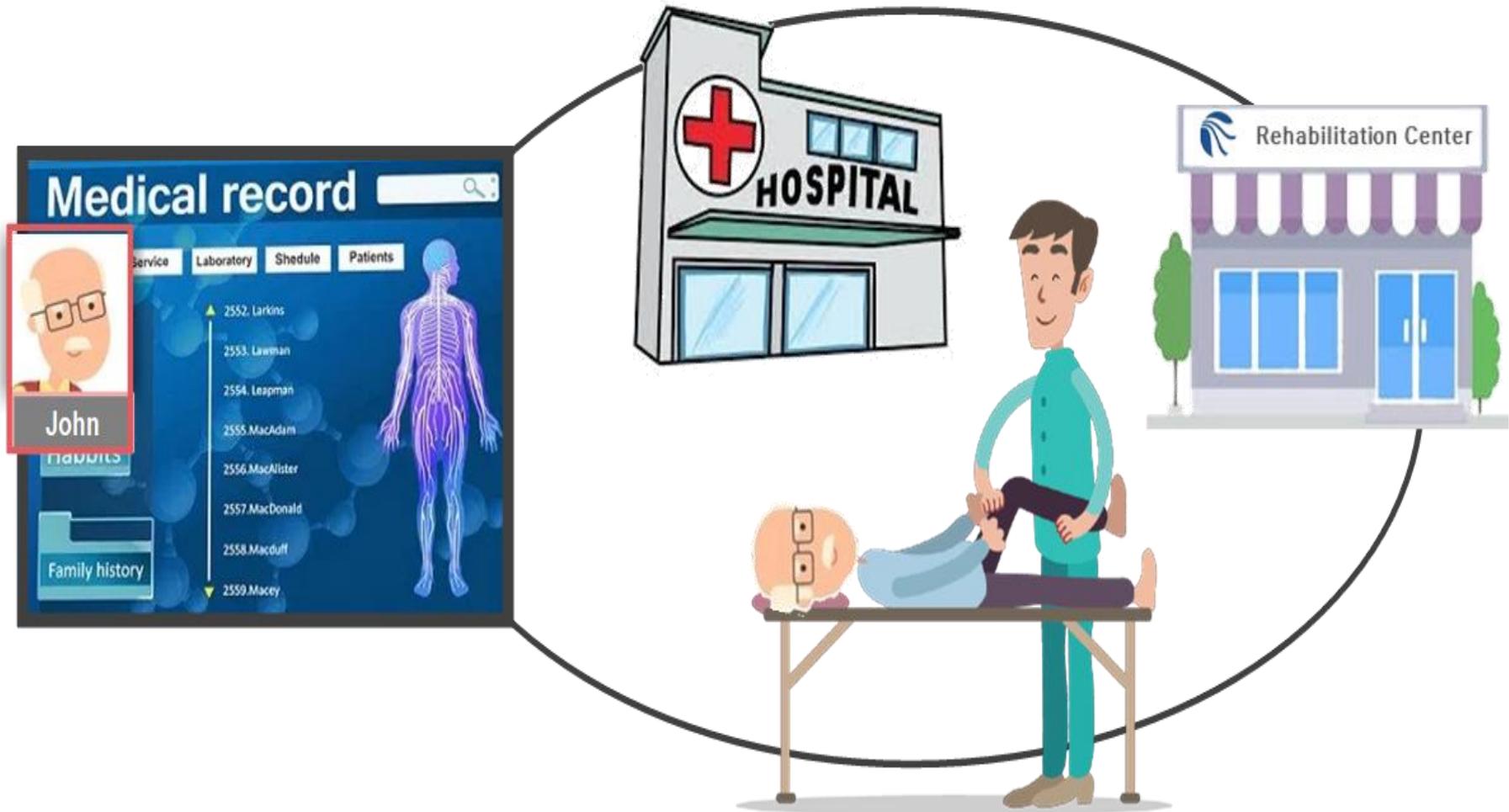
ACCESS

GUDID

IDENTIFY YOUR MEDICAL DEVICE

DI – Device Identifier
PI – Product Identifier
 - lot #, Mfg #, Exp Date, etc.

Electronic Health Records Data about Implant Moves with Patient



OpenFDA



API - an application programming interface

- + API Basics
- + Construct the Query
- + Download the API
- + Animal & Veterinary API Endpoints
- + Drug API Endpoints
- + Device API Endpoints
- + Food API Endpoints
- + Other API Endpoints

Unique Device Identifier Overview

The openFDA unique device identifier API returns data from the Global Unique Device Identification Database (GUDID), which contains information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).

UDIs are unique numeric or alphanumeric codes that consist of two parts—a device identifier (DI) and a production identifier (PI). UDIs are intended to increase electronic tracking abilities for devices involved in adverse events. Submission to the GUDID database is required for manufacturers of medical devices. 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.

To learn more about UDIs, see the [FDA's General information about UDI page](#).

Device UDIs By Distribution Status

View by: Product Codes

Each Distribution Status
as % of all Device UDIs

Display of UDIs by Product Codes for In Distribution

DI 35k 7

<https://open.fda.gov/apis/device/udi/>

OpenFDA



API - an application programming interface

- + API Basics
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- + **Device API Endpoints**
- + Food API Endpoints
- + Other API Endpoints

Unique Device Identifier Overview

The openFDA unique device identifier API returns data from the Global Unique Device Identification System (GUDID) submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).

UDIs are unique numeric or alphanumeric codes that consist of two parts—a device identifier (DI) and a production identifier (PI)—to increase electronic tracking abilities for devices involved in adverse events. Submission to the GUDID for medical devices. The FDA is establishing the unique device identification system to adequately identify devices through distribution to patient use.

To learn more about UDIs, see the [UDI General information about UDI page](#).

Device UDIs By Distribution Status

Each Distribution Status as % of all Device UDIs	Display of UDIs by Product
DI 35k	

- Device API Endpoints

- + 510(k)
- + Classification
- + Recall Enforcement Reports
- + Adverse Events
- + Pre-market Approval
- + Recalls
- + Registrations and Listings
- + Unique Device Identifier

<https://open.fda.gov/apis/device/udi/>



FDA UDI's Webpage: GUDID Enhancements and Fixes

- Global Unique Device Identification Database (GUDID)
- GUDID Guidance
- Prepare for GUDID
- Request a GUDID Account
- Submit Data to GUDID
- GUDID System Status
- GUDID Enhancements and Fixes**
- AccessGUDID (for the public)

Release 3.3 - April 10, 2021

Enhancements and Fixes	<ul style="list-style-type: none">• GUDID System will allow Coordinators to see other Coordinator Accounts and the respective Labeler DUNS associated within their organization.• GUDID System will allow Labelers and Coordinators to search their own entries in their own accounts, based on Listing Number from Advanced search page• GUDID System will allow submissions to be processed with special character – “ è ” via Web and SPL
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<https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/gudid-enhancements-and-fixes>

Content current as of 05/11/2021

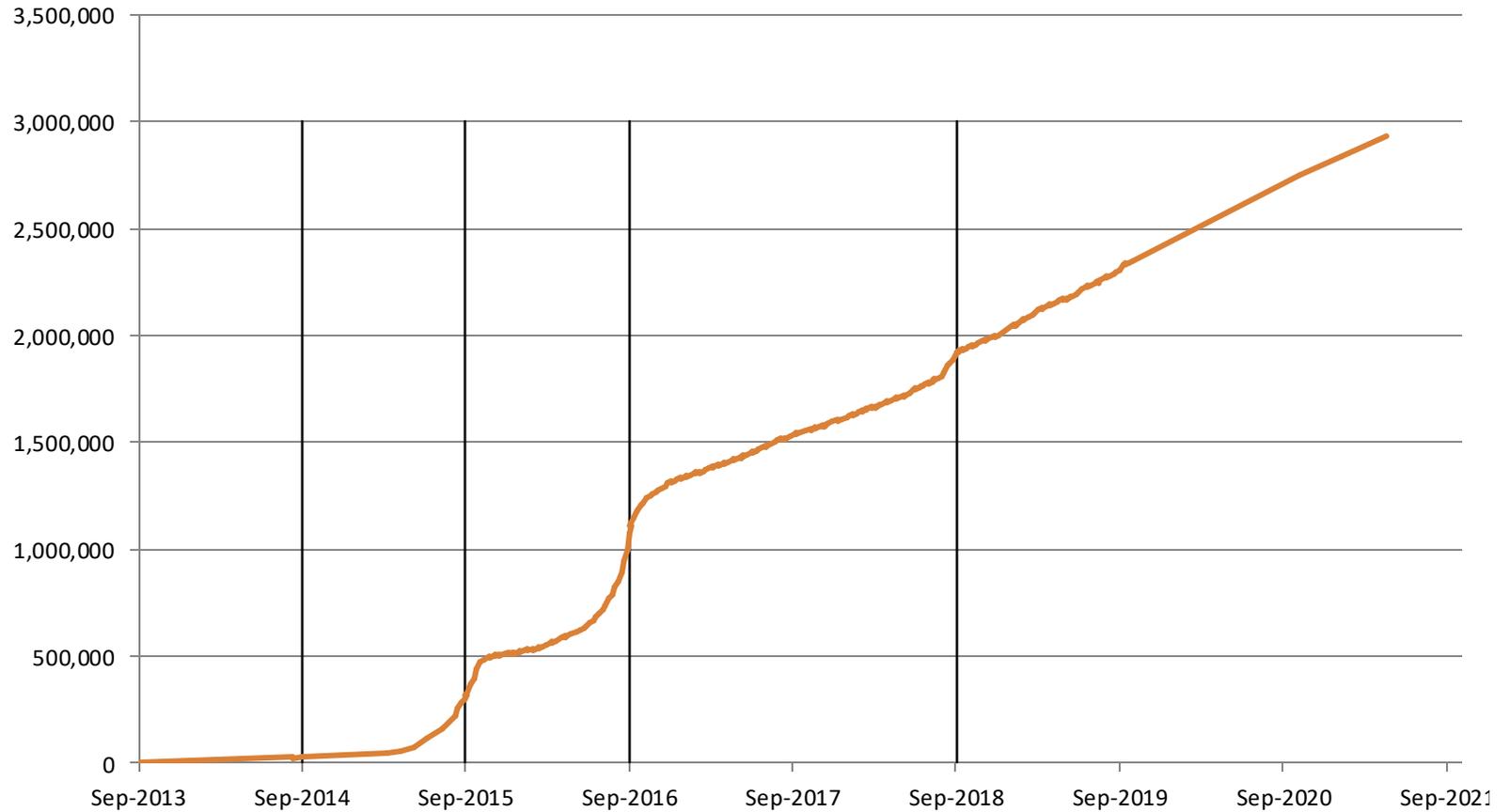
International Harmonization



GUDID Records and Submission Compliance Dates

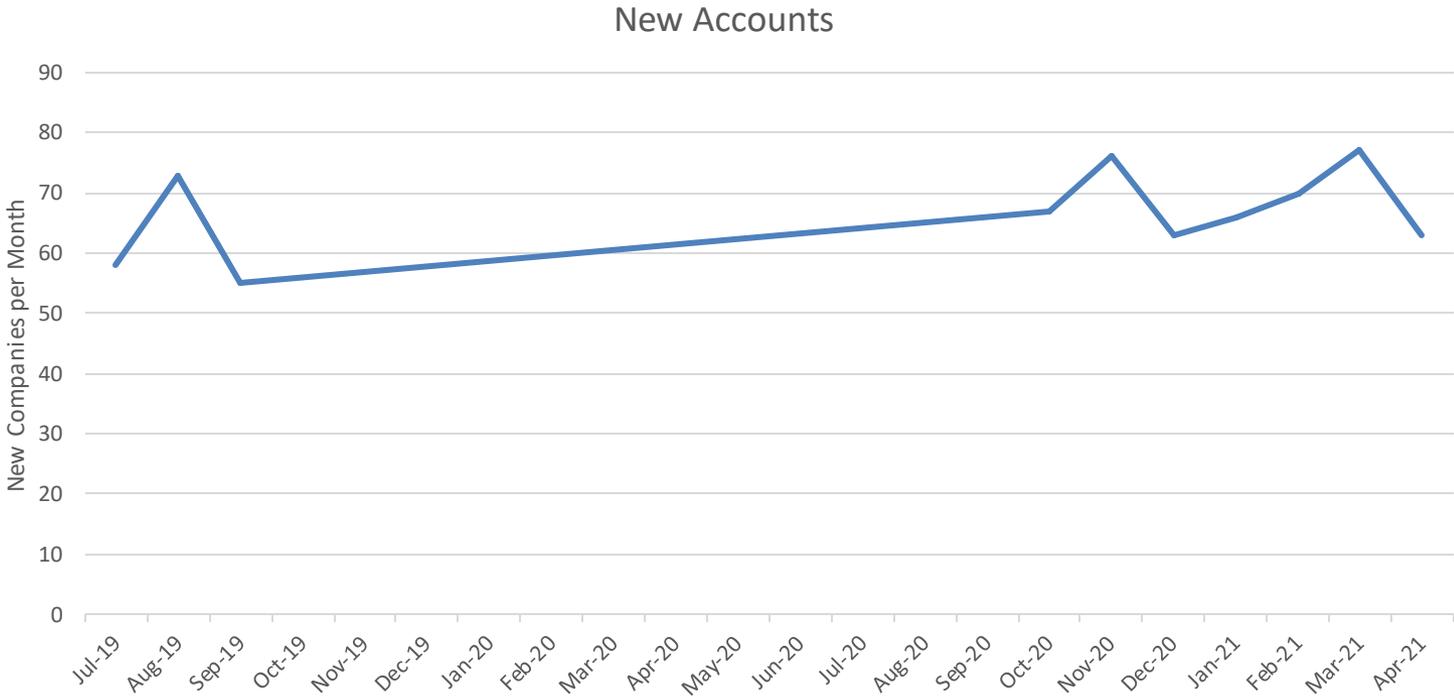


Data Current as of May 1, 2021



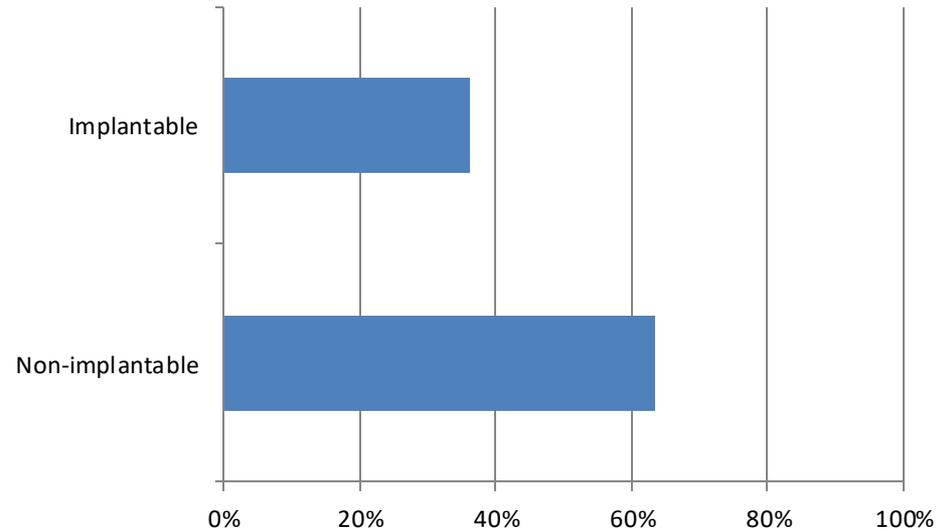
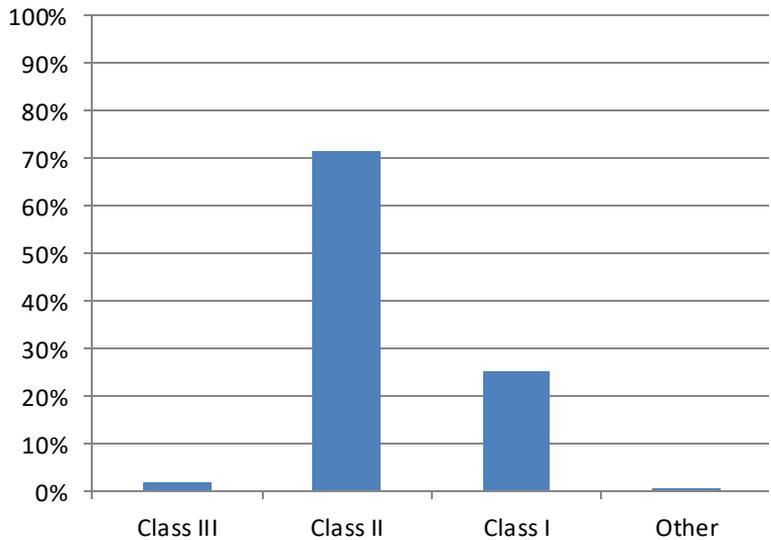
New Companies in GUDID Each Month

Data Current as of May 1, 2021



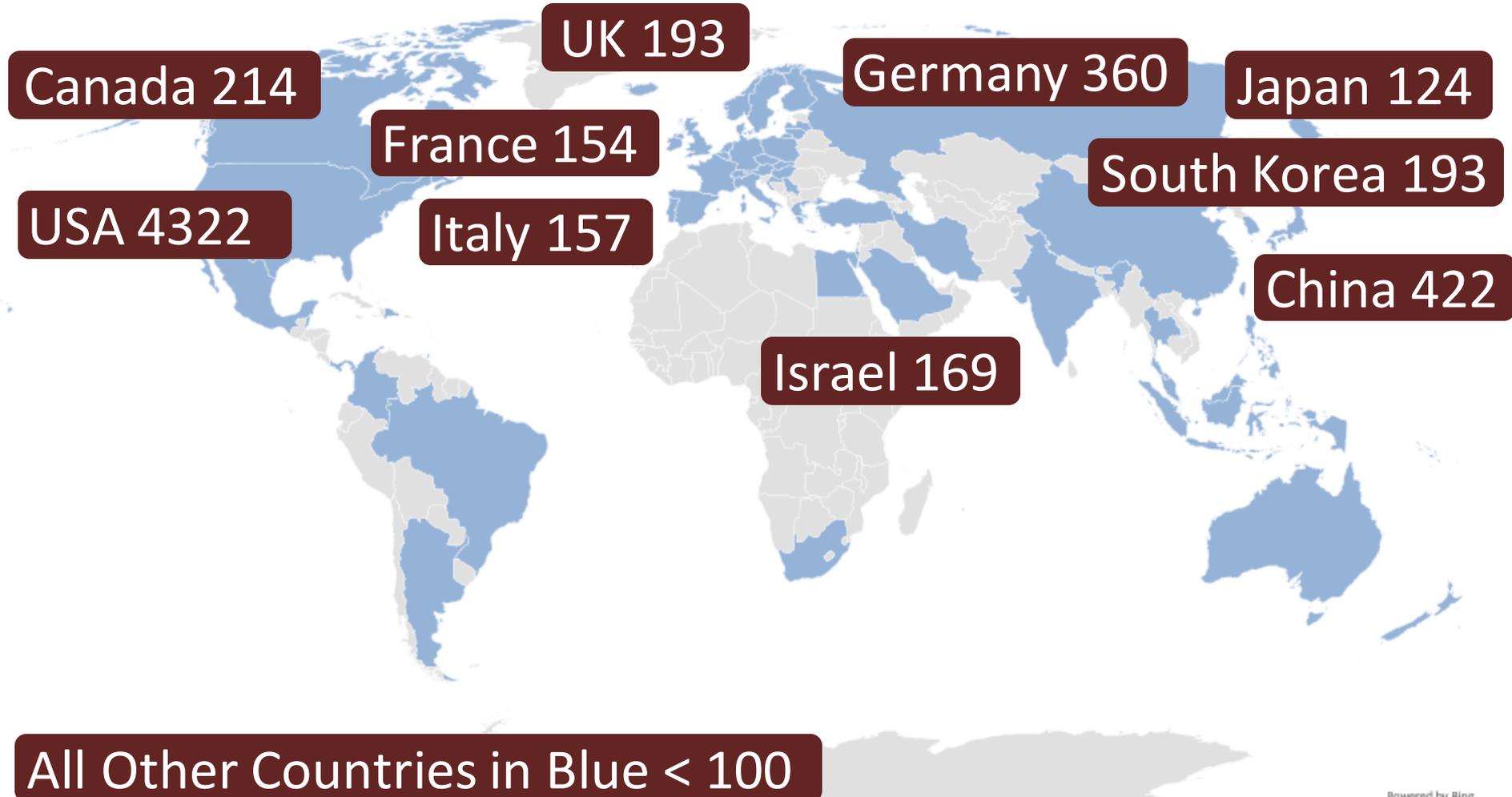
Most GUDID Records are Class II; About 37% are Associated with Implantables

*“Implantable” Devices are those Assigned FDA Product Codes Associated with Implantable Devices, Systems and Accessories
Data Current as of May 1, 2021*



GUDID Labeler Locations by Country

Data Current as of May 1, 2021



CDRH Learn

<https://www.fda.gov/training-and-continuing-education/cdrh-learn>

Resources For You

- [Device Advice](#)
- [Upcoming Medical Device Webinars and Stakeholder Calls](#)
- [Subscribe to CDRH Mailing Lists](#)
- [Follow Us on Twitter](#)
- [Division of Industry and Consumer Education \(DICE\)](#)

Start Here/The Basics! <i>MDUFA Small Business Program, Registration and Listing</i>	▼
How to Study and Market Your Device - (New module 5/20/21) <i>510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification</i>	▼
Postmarket Activities - (New modules 4/15/21) <i>Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization</i>	▼
Unique Device Identification (UDI) System	▲
1. Unique Device Identification (UDI) System Regulatory Overview Presentation Printable Slides Transcript	
2. Global Unique Device Identification Database (GUDID) Account Request: Preparation and Process Presentation Printable Slides Transcript	
3. The GUDID Device Identifier (DI) Record Presentation Printable Slides Transcript	





FDA UDI's Webpage (UDI System - FDA Help Desk)

<https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/fda-udi-help-desk>

- Unique Device Identification System (UDI System)
- UDI Basics
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- UDI Exceptions, Alternatives and Time Extensions
- UDI Rule and Guidances, Training, Resources, and Decisions
- FDA UDI Help Desk**
- Global Unique Device Identification Database (GUDID)

FDA UDI Help Desk

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You may find answers to your questions on the [UDI Basics web page](#), including:

- [Am I a device labeler?](#)
- [Understanding the UDI format](#)
- [Developing a UDI using an FDA-accredited issuing agency's system](#)
- [Meeting compliance dates and requirements](#)
- [Understanding exceptions, alternatives, and time extensions](#)
- [Submitting information to the GUDID database](#)
- [Searching the AccessGUDID database](#)

If you have specific questions related to UDI and GUDID, complete the following information to submit your question to the FDA UDI Help Desk.

Contact the FDA UDI Help Desk



Definitions and Acronyms

- **GUDID** - Global Unique Device Identification Database
- **NLM** – National Library of Medicine
- **API** - an application programming interface is an interface that defines interactions between multiple software applications or mixed hardware-software intermediaries.
- **IA** - Issuing Agency
- **IMDRF** - International Medical Device Regulators Forum
- **AIDC** - Automatic identification and data capture refers to the methods of automatically identifying objects, collecting data about them, and entering them directly into **computer** systems, without human involvement.



THANK YOU!

Any Questions?