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

Understanding UDI & the latest deadlines.

CDR Stephen Smith, CSO - June 2021

Goals

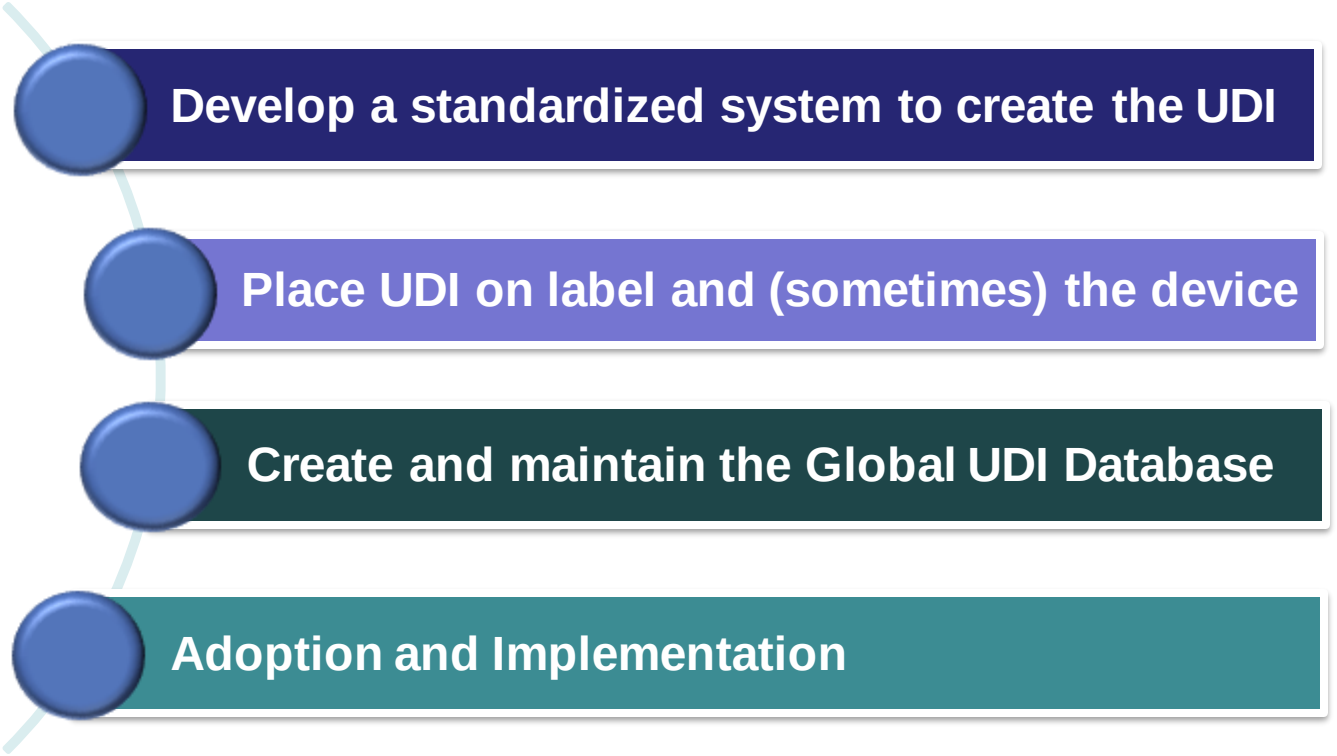
- UDI History & Current guidance
- Extensions to some timelines
- Sources/Links for UDI info
- What to expect from the inspection process…

Establishing a UDI System

UDI Final Rule

[78 FR 58786]

Sept 24, 2013



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 **E**lectronic **H**ealth **R**ecords & 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

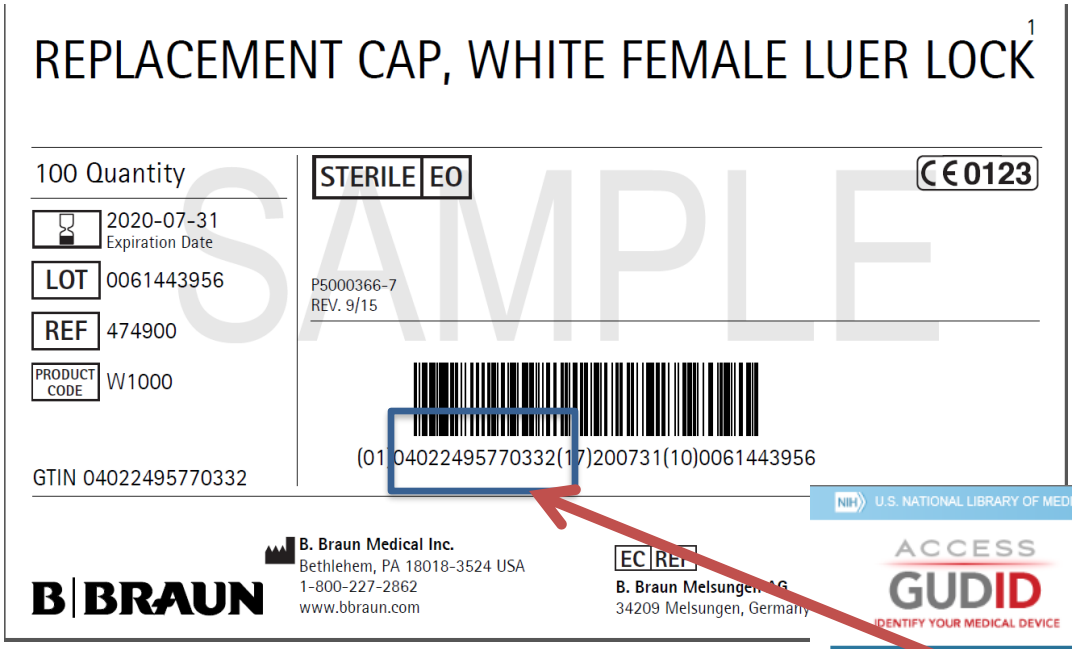
2020 Guidance

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.

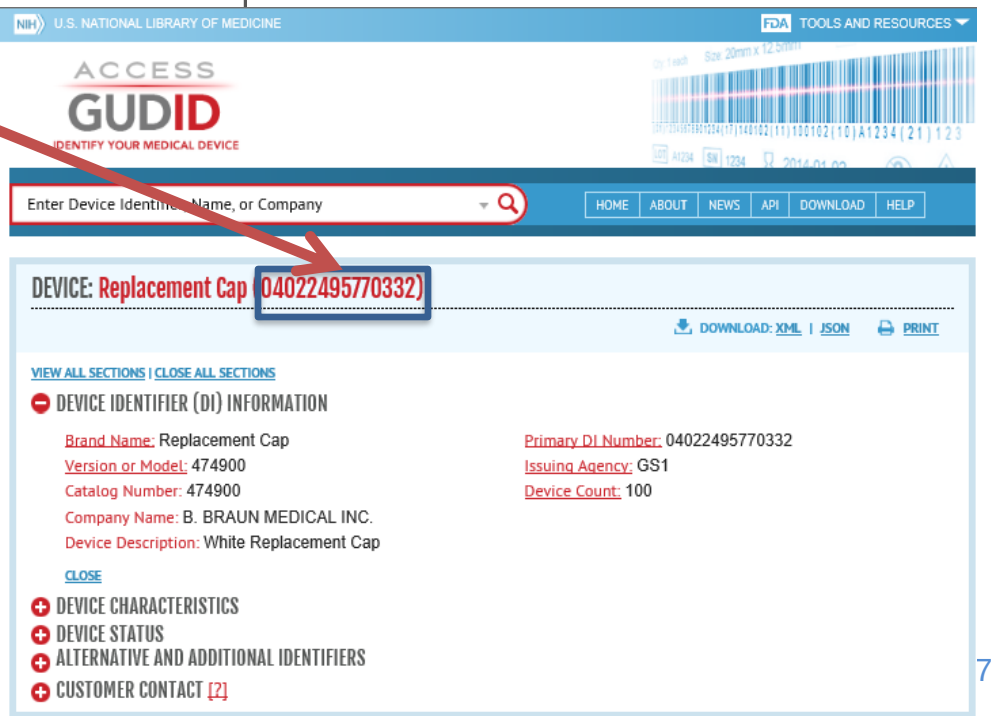
What is the UDI?



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

Code in plain text and machine readable format (AIDC)

=/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

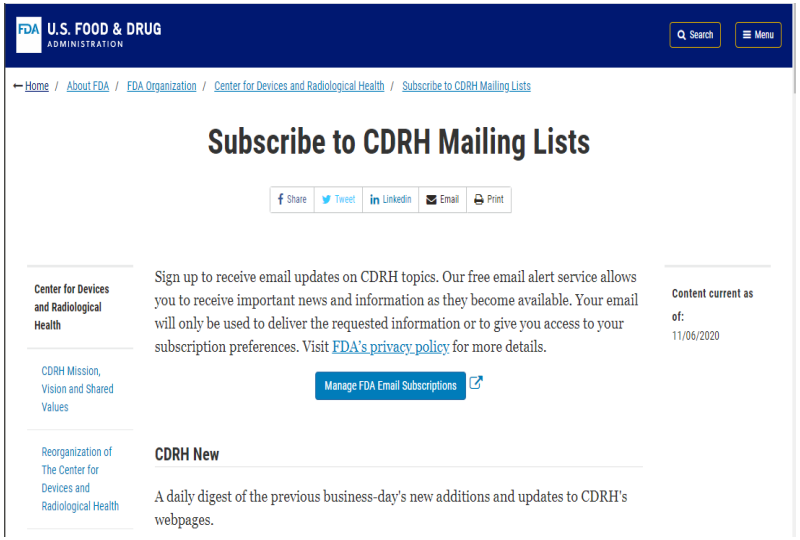
Global Unique Device Identification Database (GUDID)

News and Updates

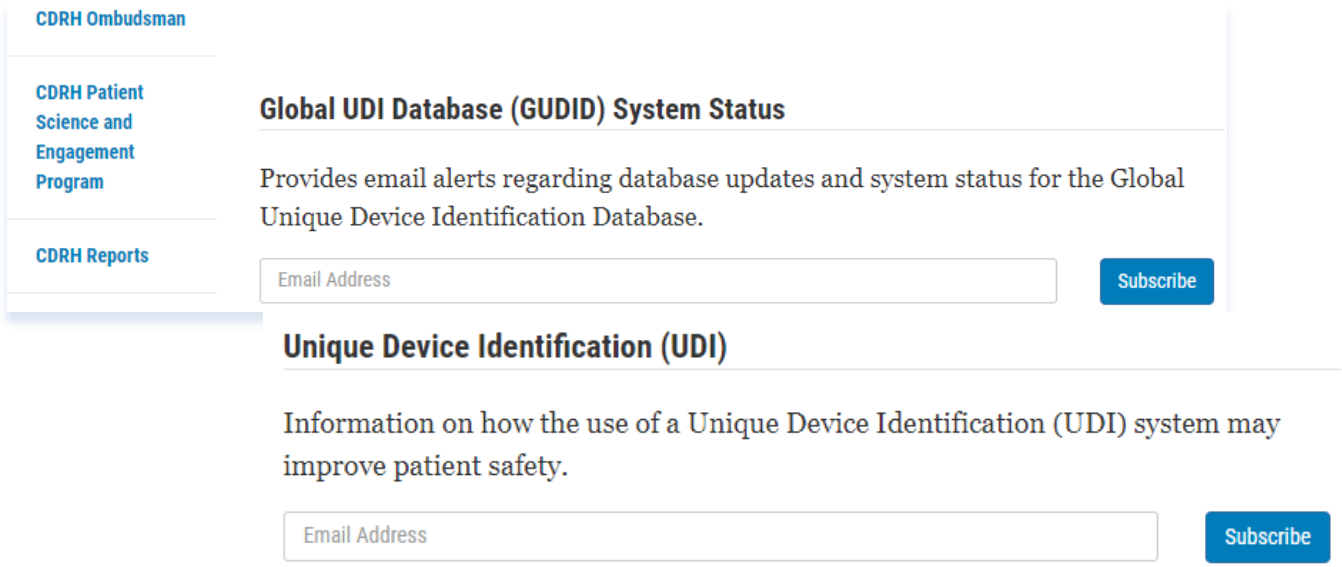
In May 2021, the FDA issued the guidance Enforcement Policy Regarding Use of National Health Related Item Code (NHRIC) and National Drug Code (NDC) Numbers on Device Labels and Packages. The guidance explains that the FDA does not intend to object to the use of legacy NHRIC and NDC numbers on device 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

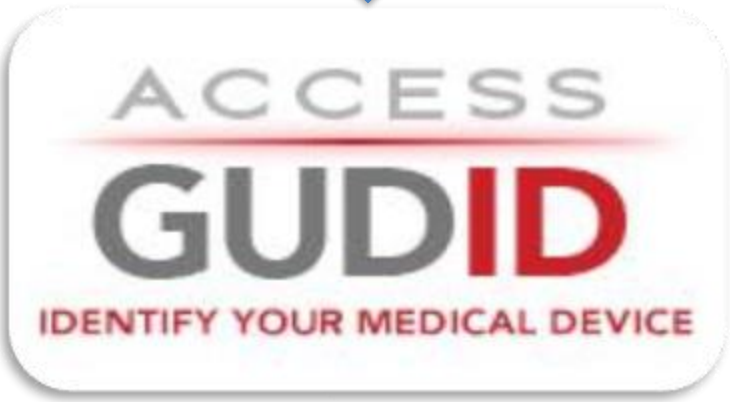
FDA Email Notifications Info from:



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



Data Submission



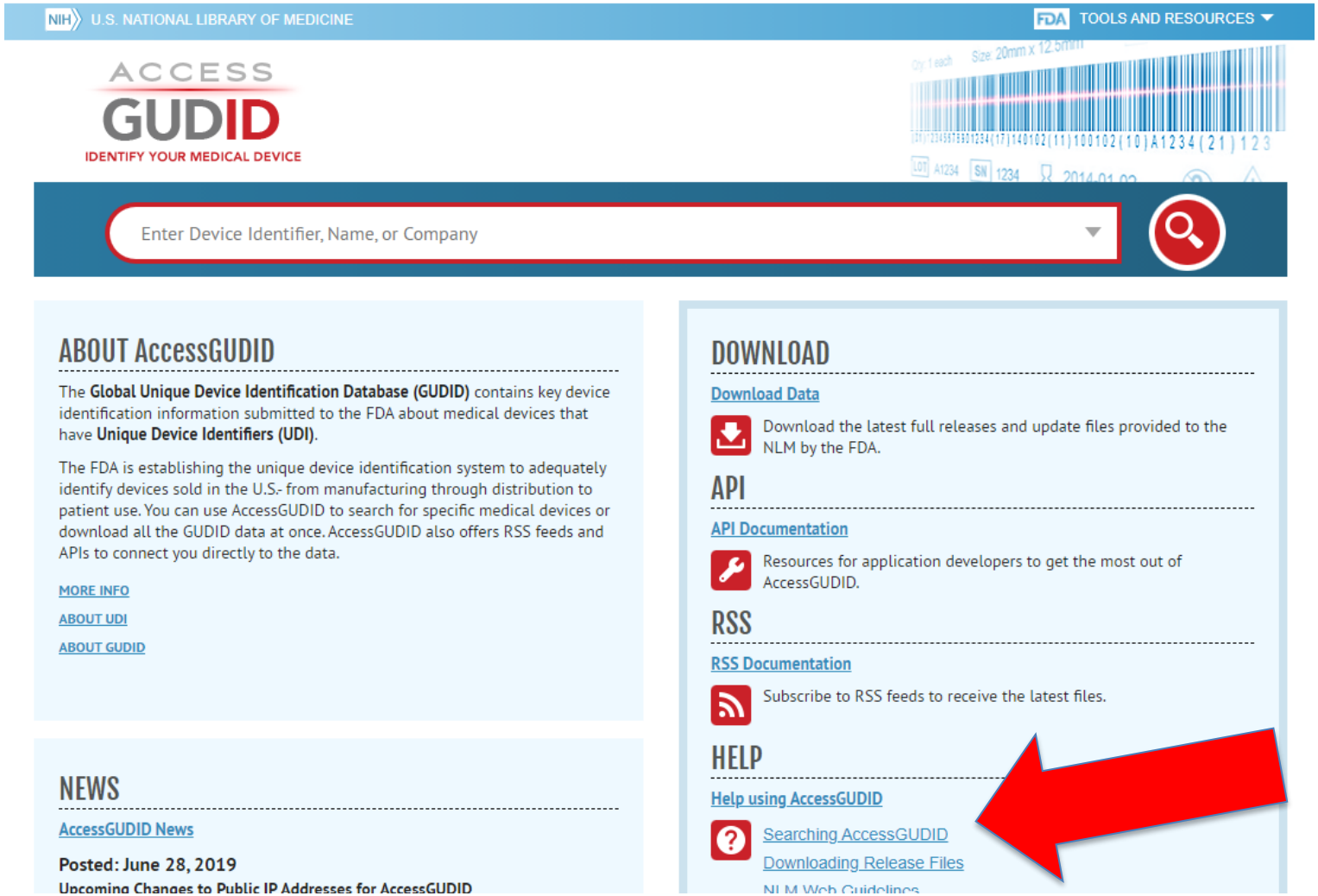
Data Use

Reference device identification information

Submit once – reuse in downstream systems

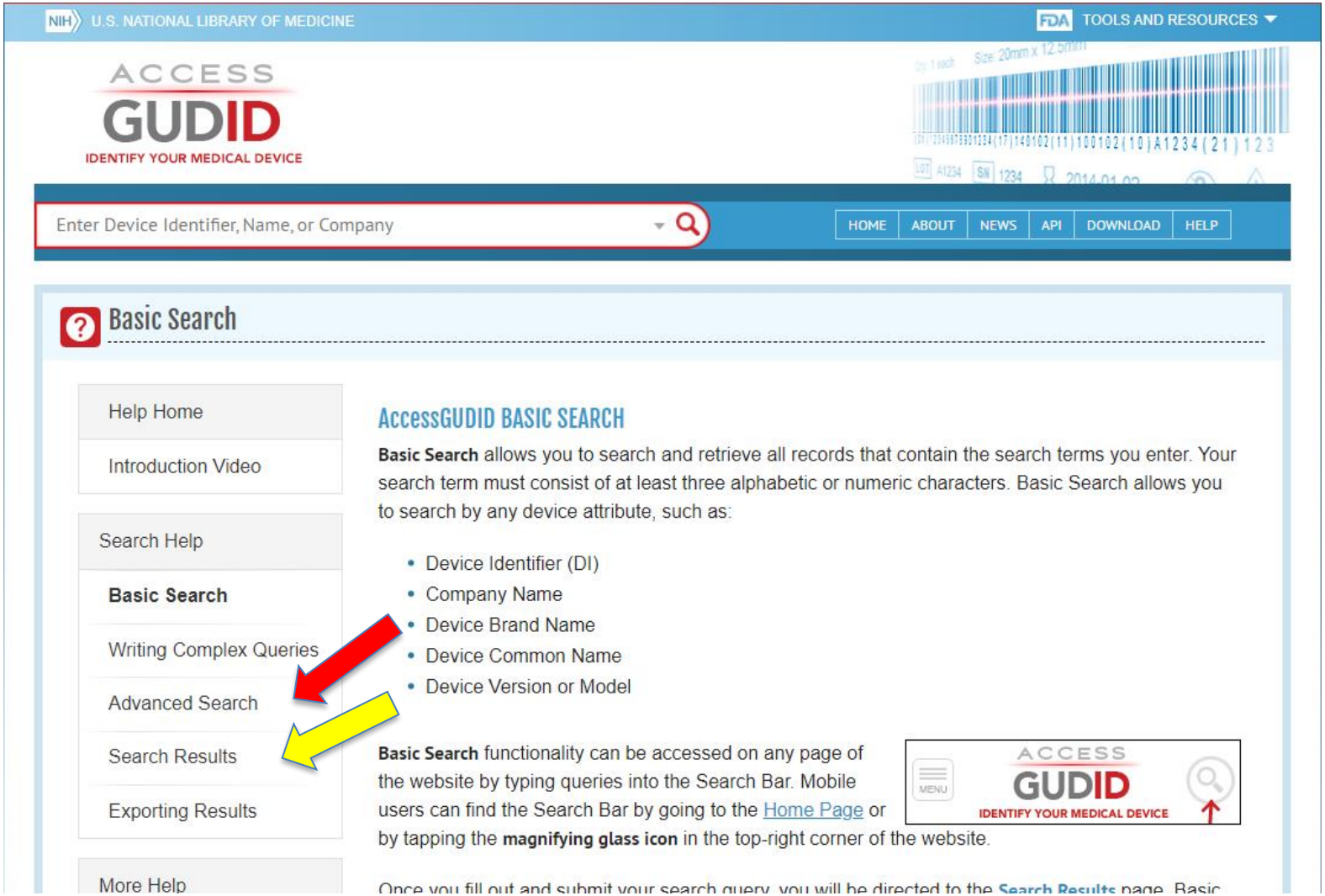
Optimize data quality based upon use

AccessGUDID website (home page)

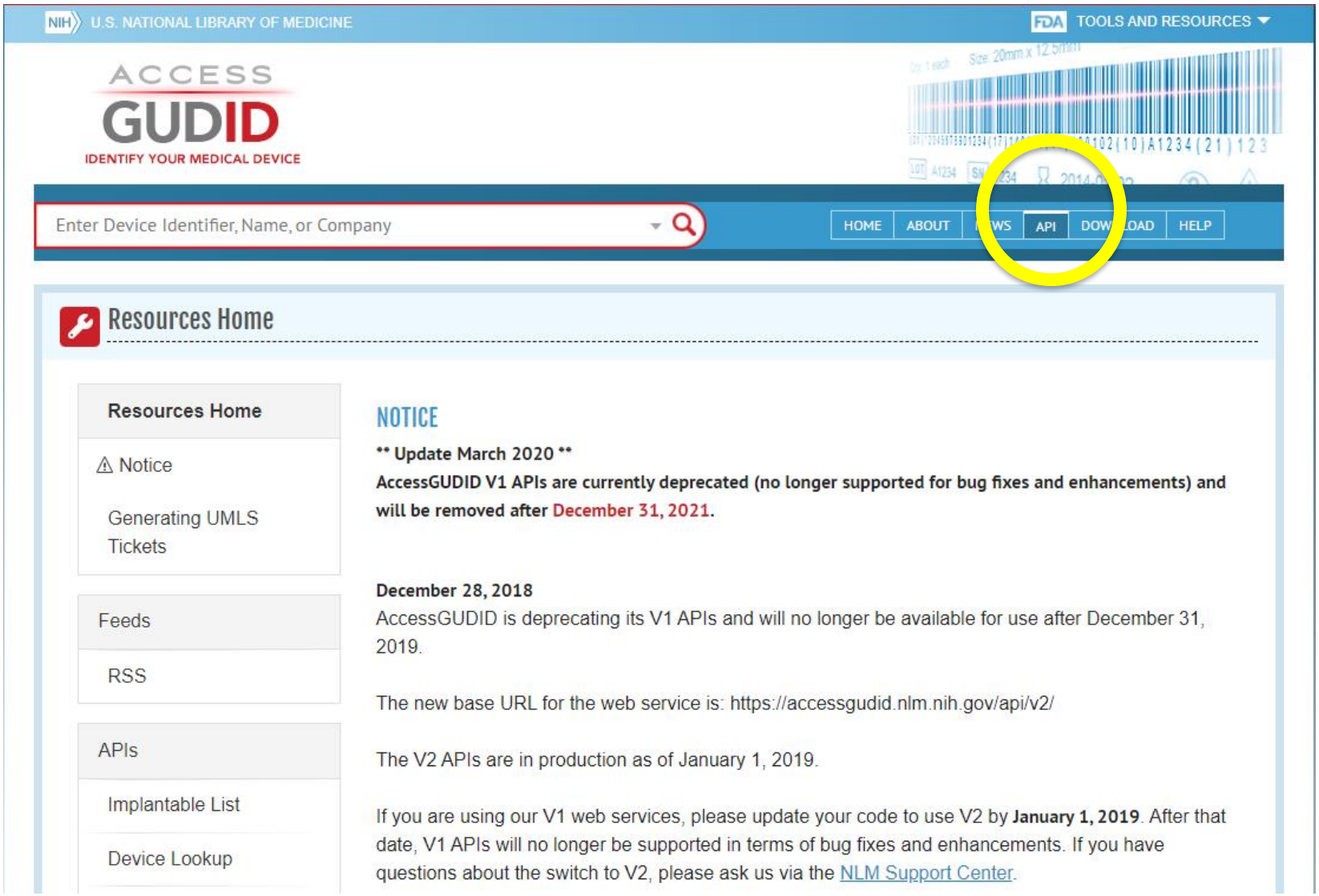


https://accessgudid.nlm.nih.gov/

AccessGUDID (Basic Search)



AccessGUDID (API's)



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]

See Related Information

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

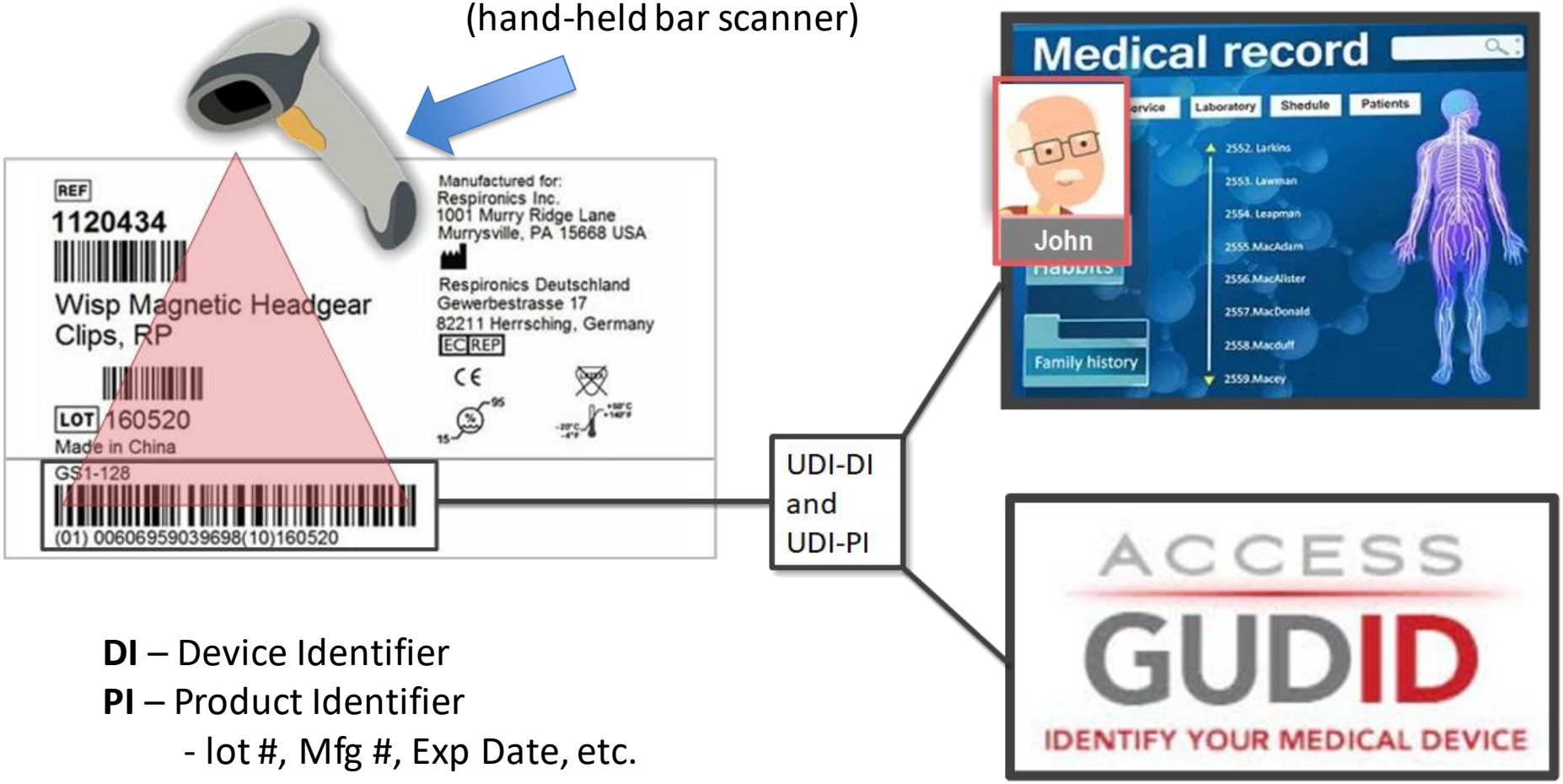
Subpart E - Global Unique Device Identification Database

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.

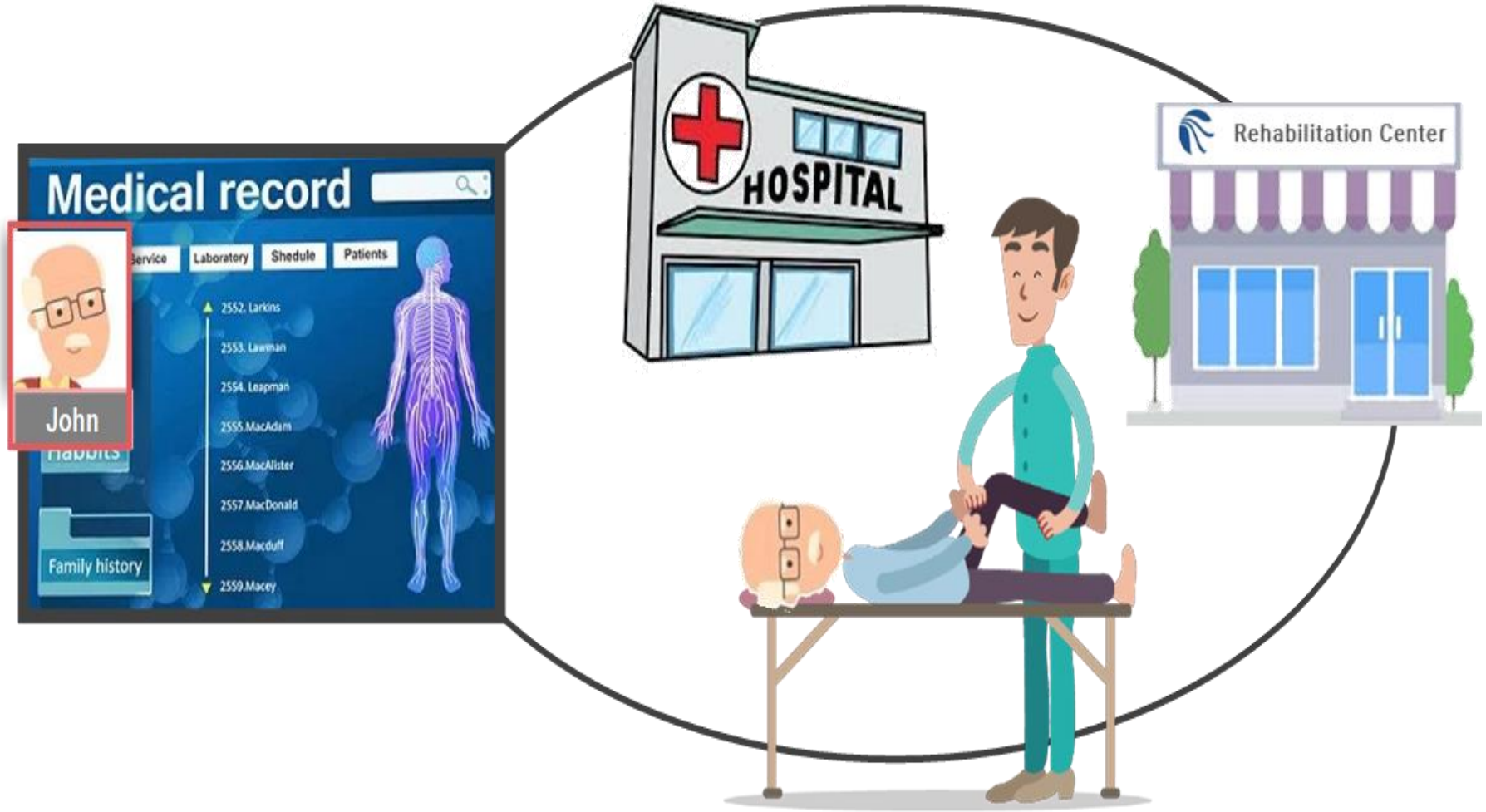
(b) The labeler of a device shall submit to FDA an update to the information required by § 830.310 whenever the information changes. The updated information must be submitted no later than the date a device is first labeled with the changed information. If the information does not appear on the label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

Transfer essential device information to other Health Systems



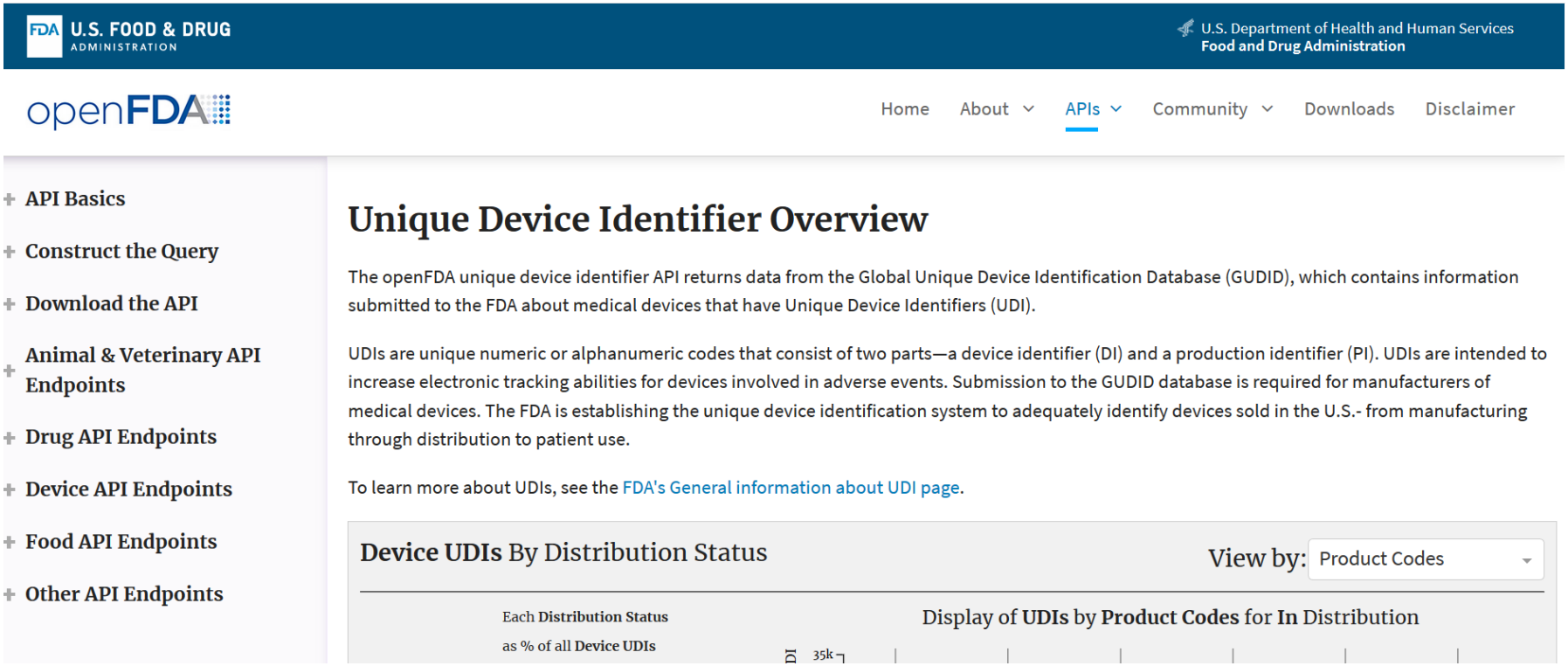
DI – Device Identifier
PI – Product Identifier
- lot #, Mfg #, Exp Date, etc.

Electronic Health Records Data about Implant Moves with Patient



OpenFDA

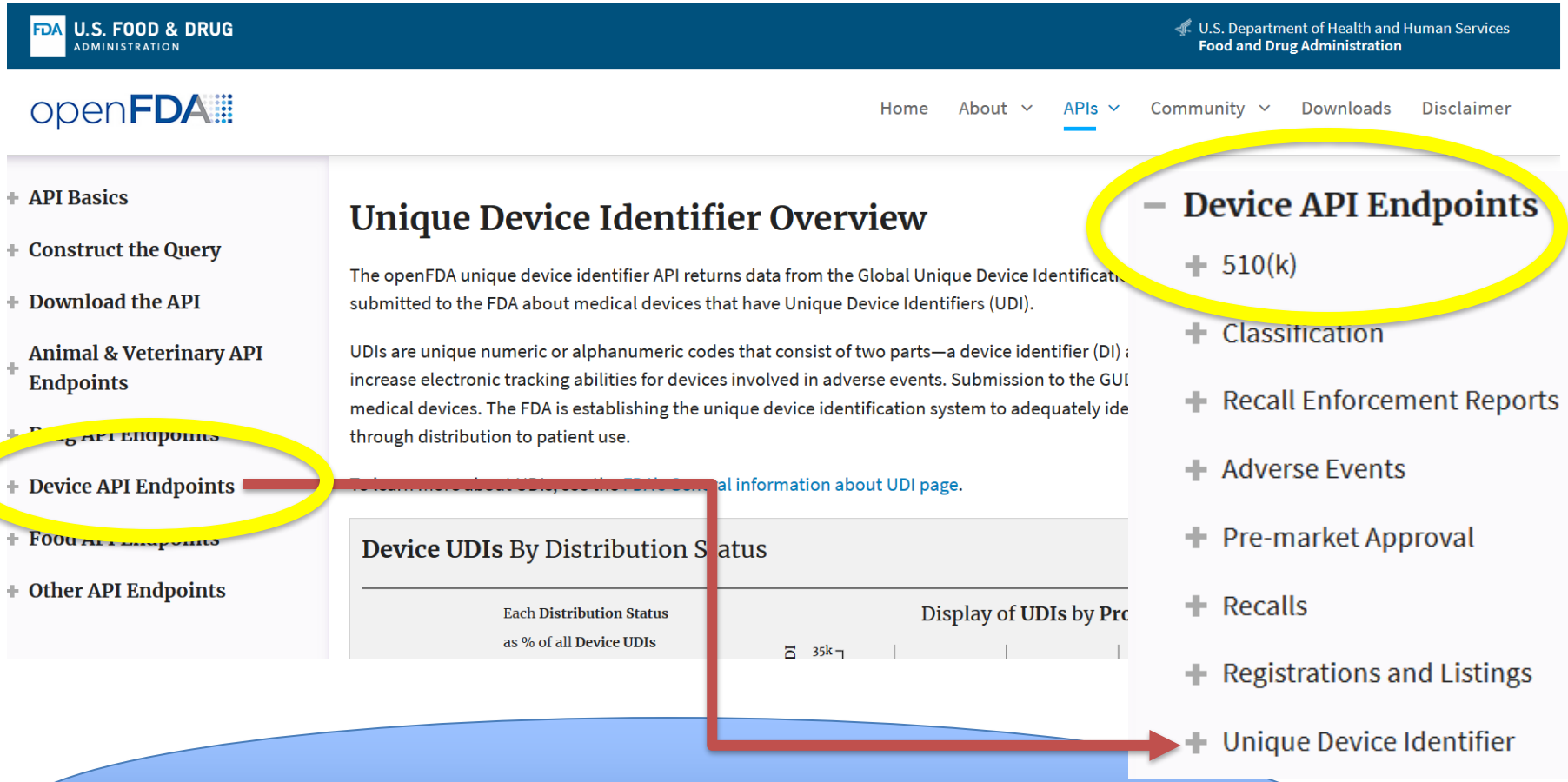
API - an application programming interface



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

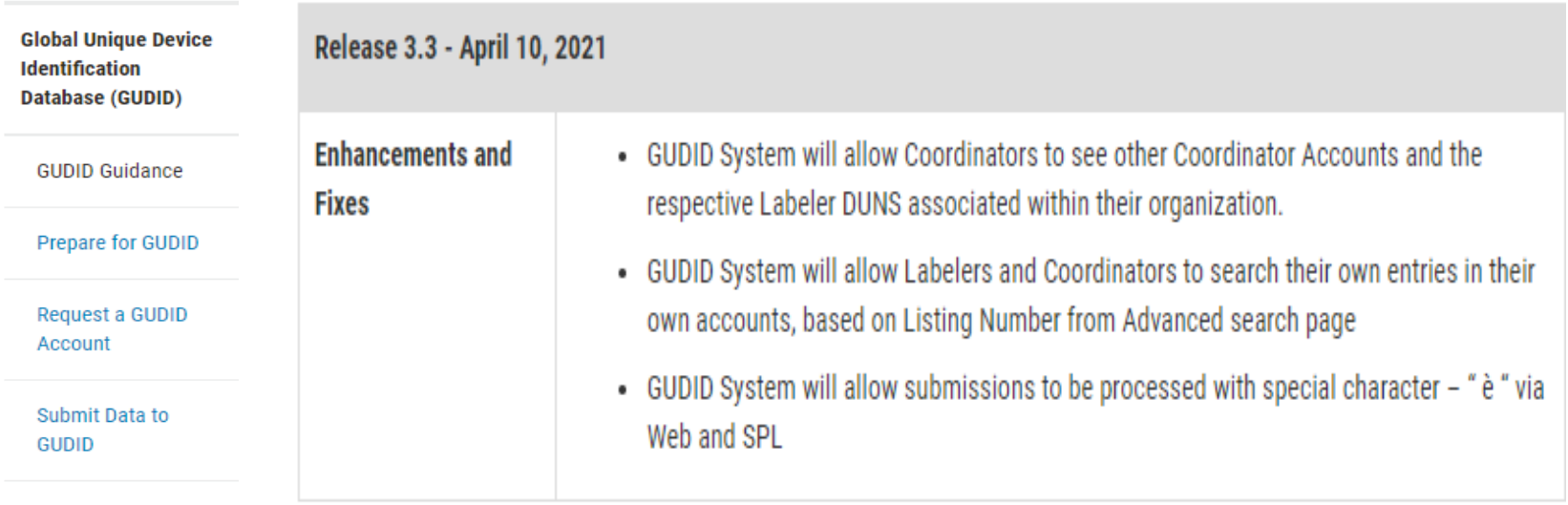
OpenFDA

API - an application programming interface



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	• 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

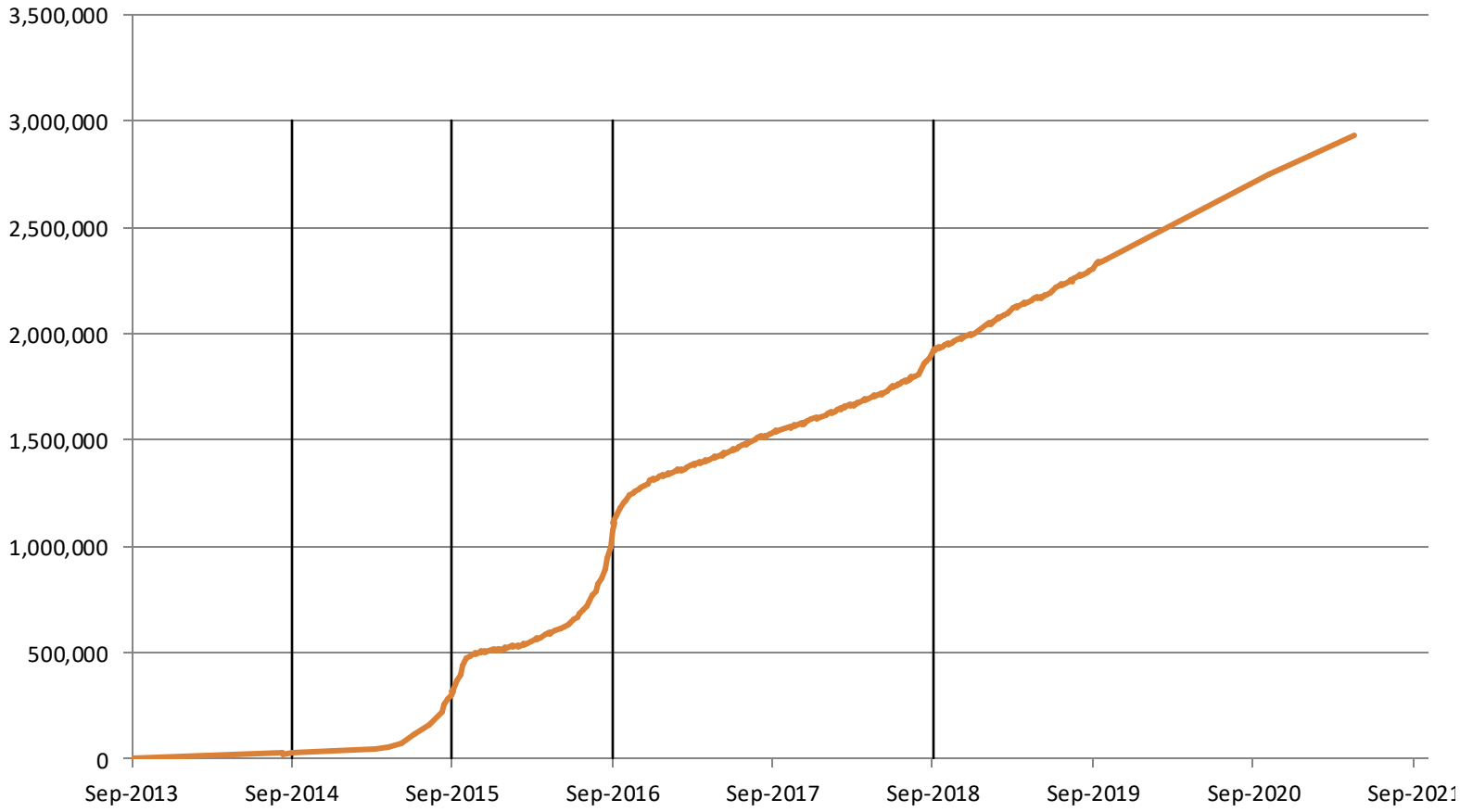
https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/gudid-enhancements-and-fixes

Content current as of 05/11/2021

International Harmonization

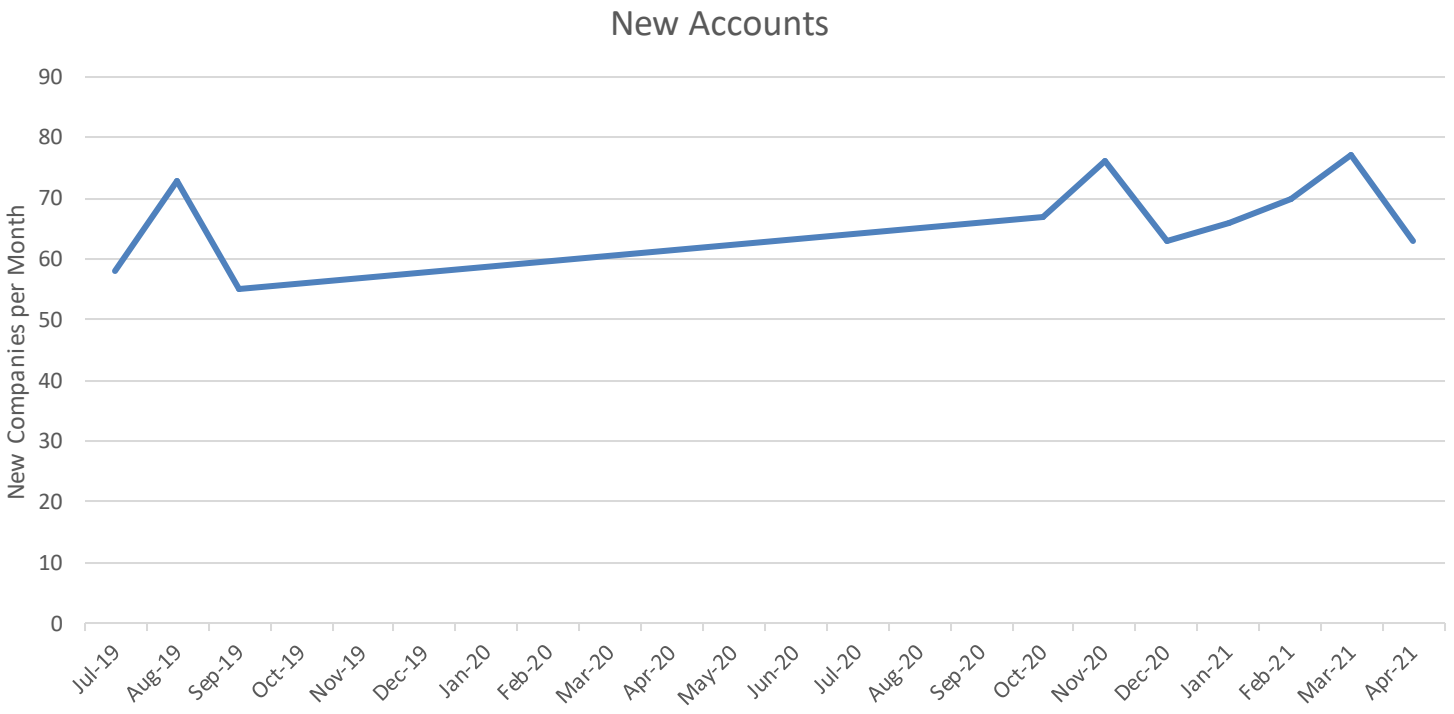
GUDID Records and Submission Compliance Dates

Data Current as of May 1, 2021



New Companies in GUDID Each Month

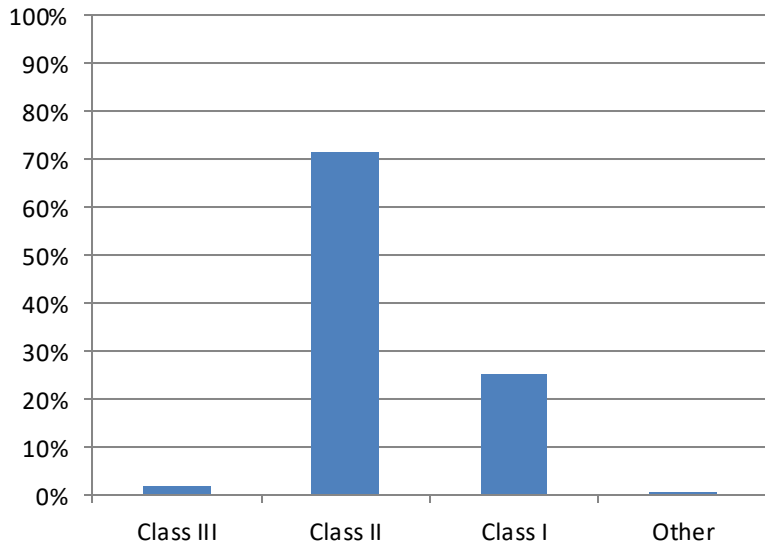
Data Current as of May 1, 2021

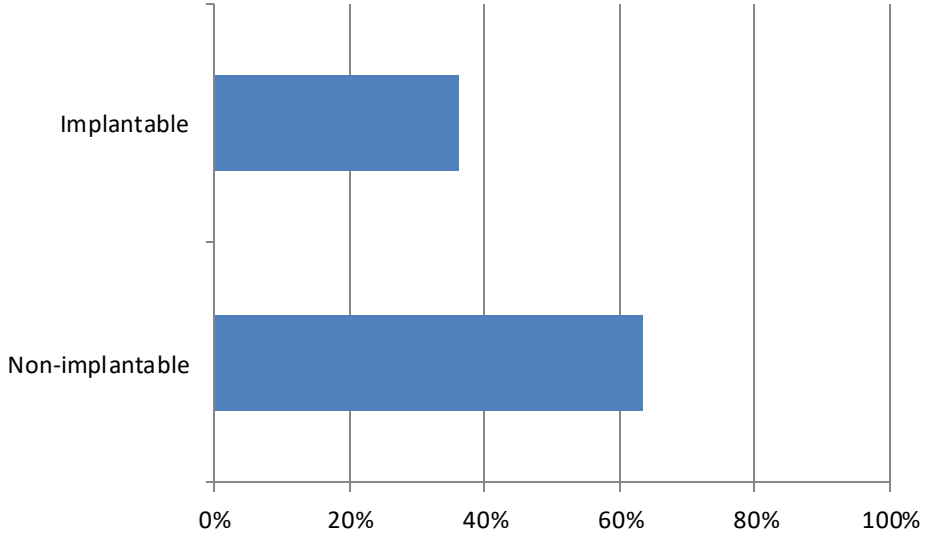


Most GUDID Records are Class II; About 37% are Associated with Implantables

"Implantable" Devices are those Assigned FDA Product Codes Associated with Implantable Devices, Systems and Accessories

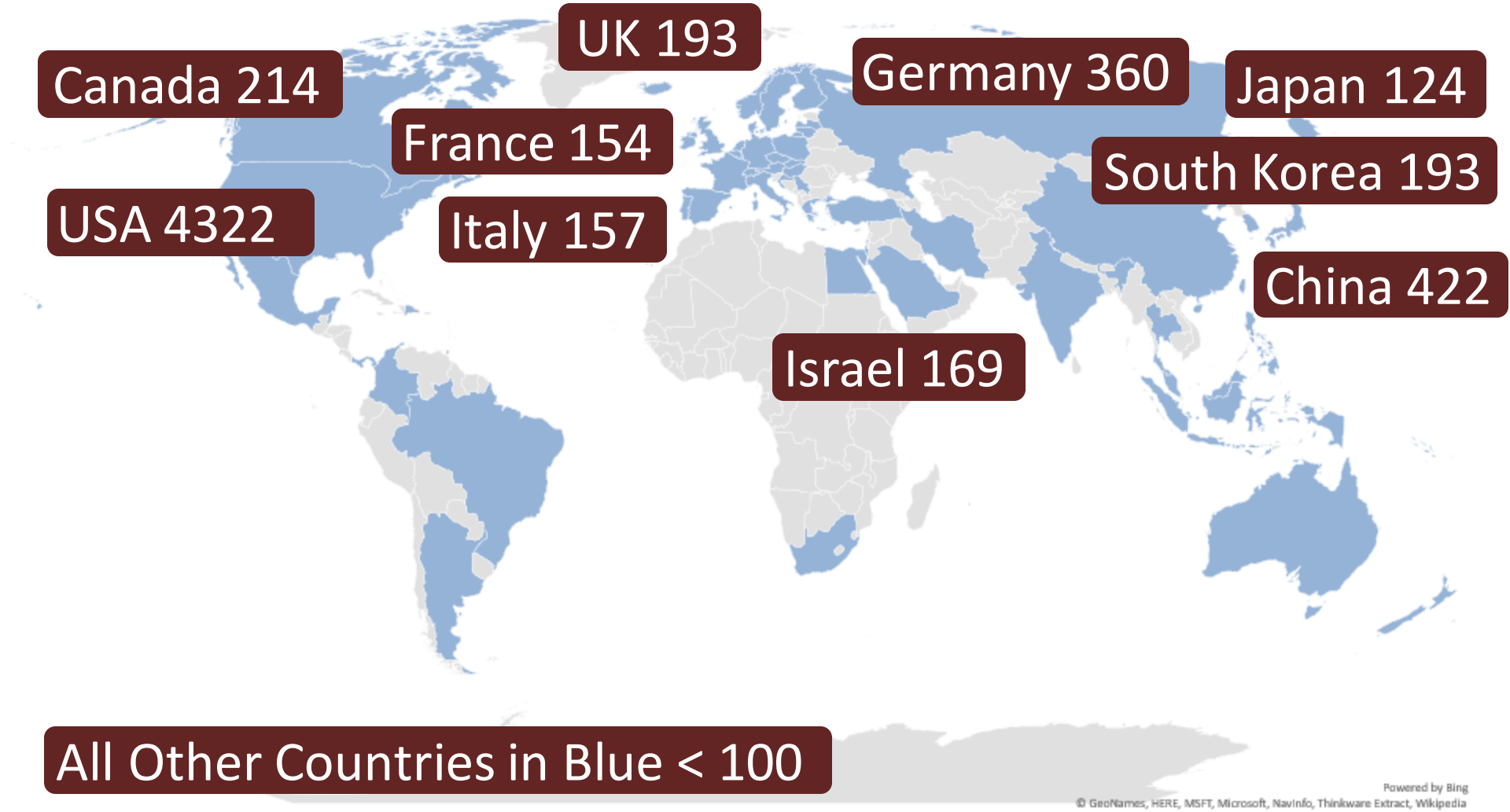
Data Current as of May 1, 2021





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!
MDUFA Small Business Program, Registration and Listing

How to Study and Market Your Device - *(New module 5/20/21)*
510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification

Postmarket Activities - *(New modules 4/15/21)*
Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization

Unique Device Identification (UDI) System

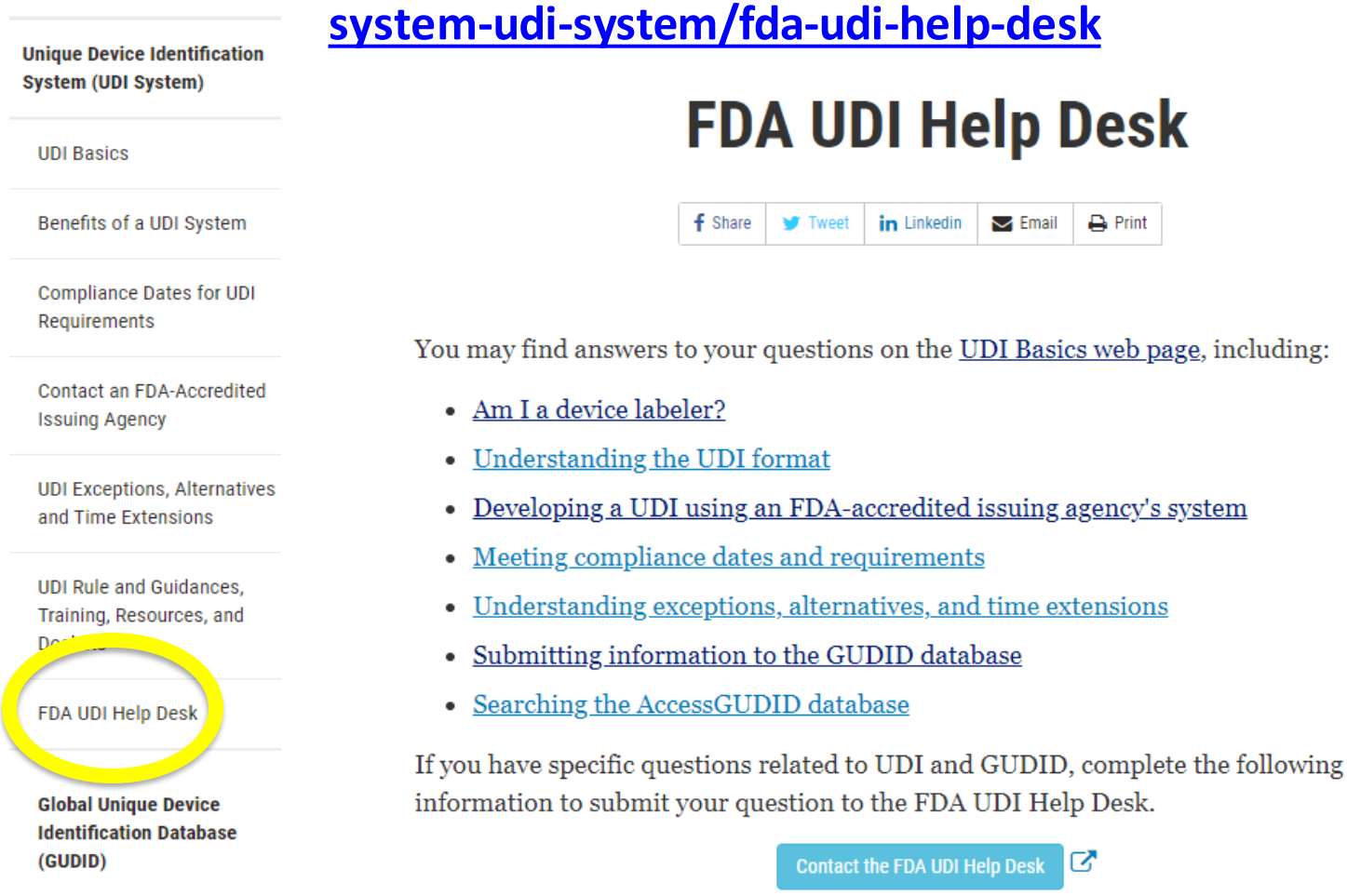
1. Unique Device Identification (UDI) System Regulatory Overview
Presentation Printable Slides Transcript

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



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?