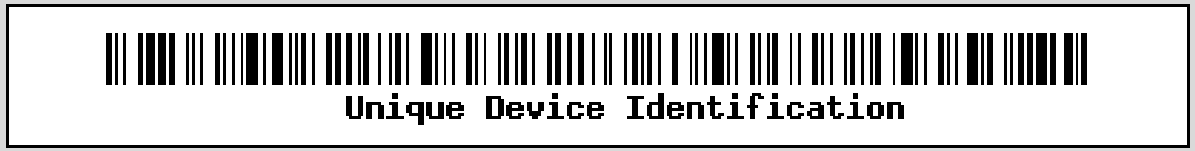
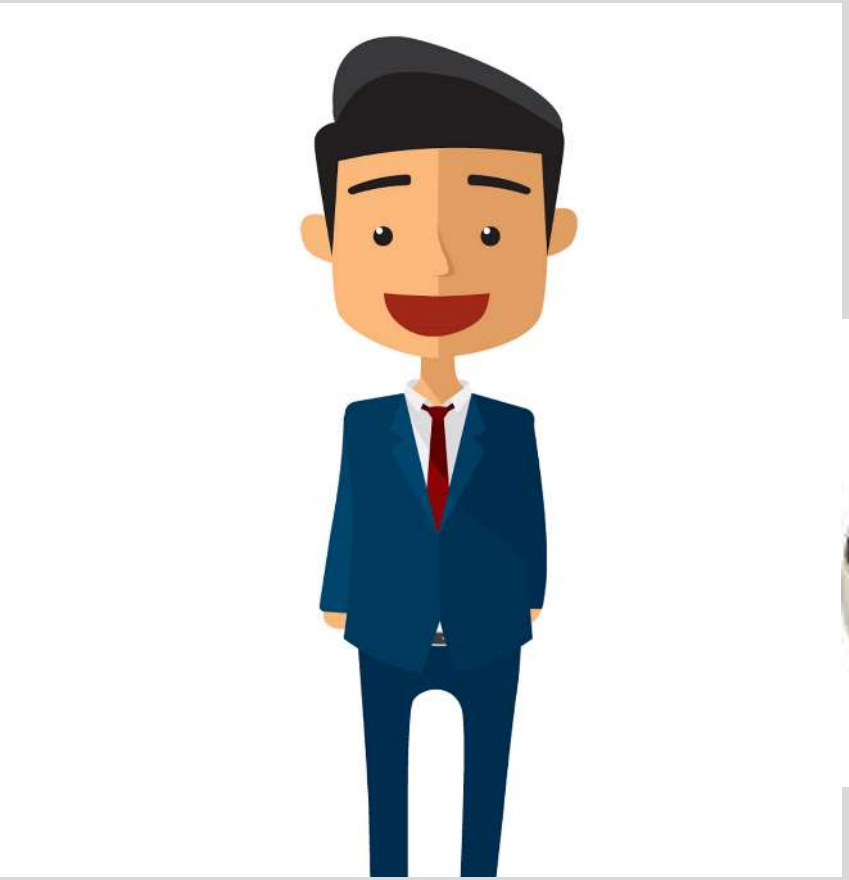
Unique Device Identification



FDA Small Business
Regulatory Education for Industry (REdI)
Burlingame, CA
May 16, 2018

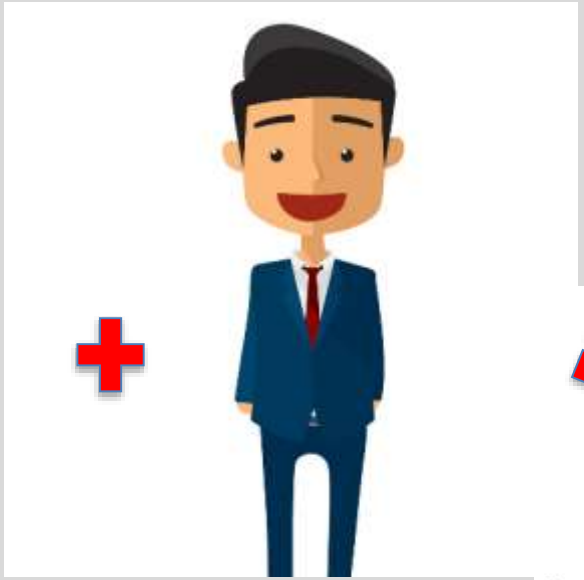
Loretta E. Chi, JD
Office of Center Director, Informatics
Center for Devices and Radiological Health
U.S. Food and Drug Administration

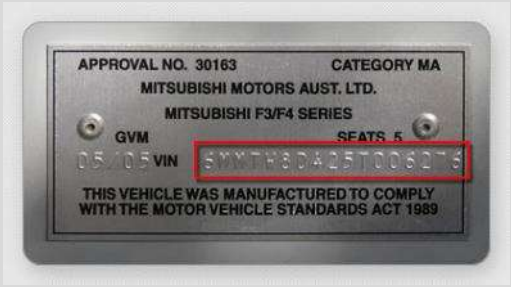
Once upon a time…



OH NO!

Keys to Identification





Barcode Identifiers Are Not New

Learning Objectives

- Learn about the UDI Program background, the program objectives and basic requirements
- Identify milestones achieved to date
- Understand some of the key policy decisions issued through alternatives, letters to industry and guidance documents
- Know the importance of data quality in the Global Unique Device Identification Database (GUDID)

Program Background

Applies to all devices unless an exception or alternative applies.

Devices
201(h) of FD&C Act

…instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory…

Label to Bear a UDI
21 CFR 801.20

The label of every medical device shall bear a unique device identifier (UDI)…Every device package shall bear a UDI…

Program Objectives

"Establish a system to adequately identify devices through distribution and use"

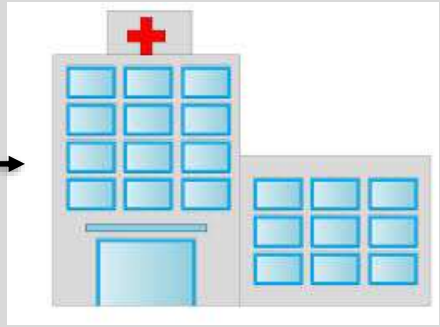
- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Allow more accurate reporting, reviewing, and analyzing of adverse event reports
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries
- Enable more effectively managed medical device recalls

Adequately Identify

To Point of Use

Through Entire Health Care System

From Point of Distribution



UDI Adoption

UDI Labeled Device to Care Provider

Device used on patient

Document Device Use

Vision for UDI Adoption

Company submits data to GUDID

GUDID as source of standard device information

FDA

Basic Summary of UDI Requirements

Unique Device Identification (UDI) System Regulatory Overview

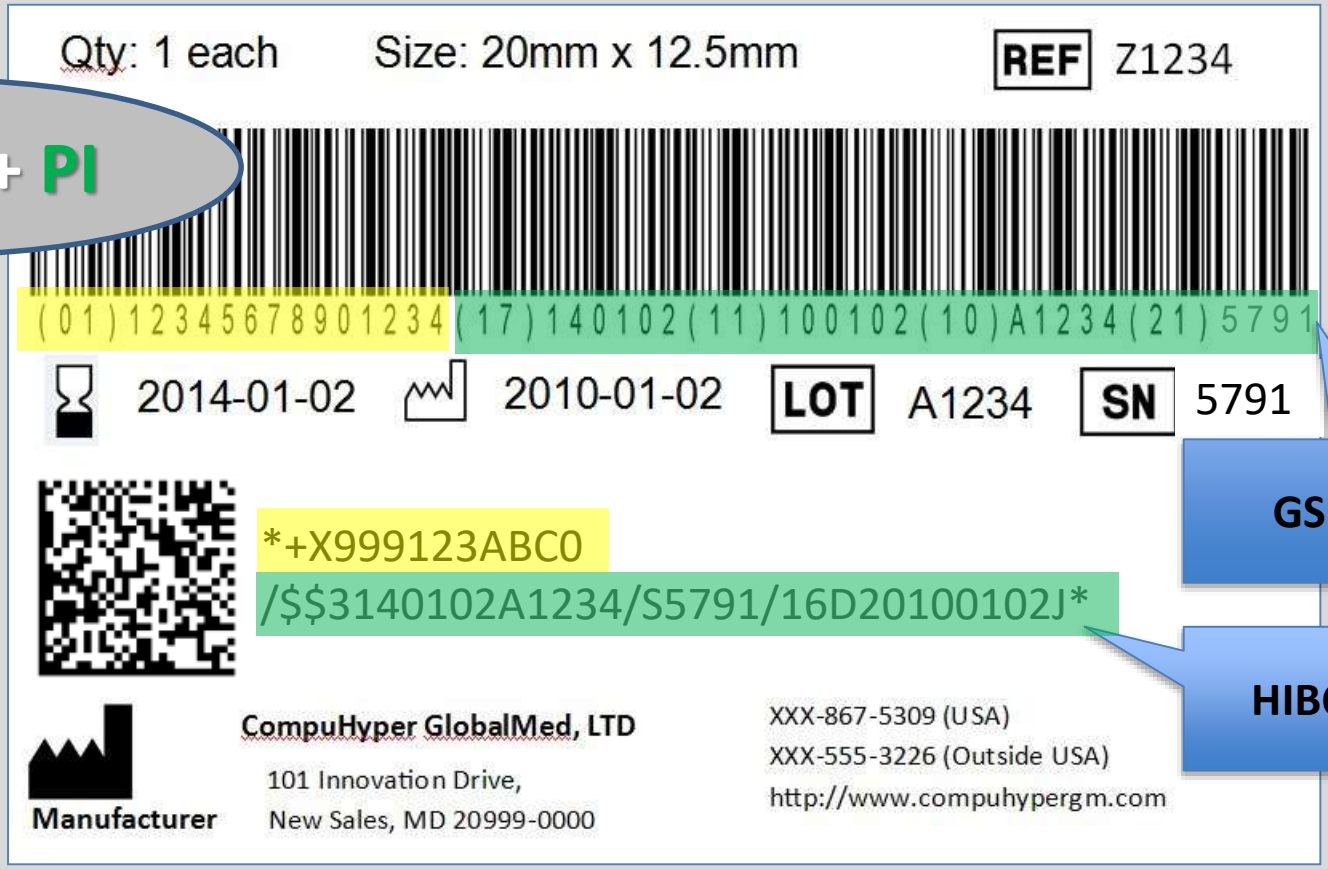
Presentation Printable Slides Transcript

What is a UDI?

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

Code in plain text and machine readable format (AIDC)

UDI = DI + PI



Key data must be submitted to GUDID

The GUDID Device Identifier (DI) Record

Presentation Printable Slides Transcript

Global Unique Device Identification Database (GUDID) Account Request: Preparation and Process

Presentation Printable Slides Transcript

Milestones Achieved to Date

Implementation Timeframe

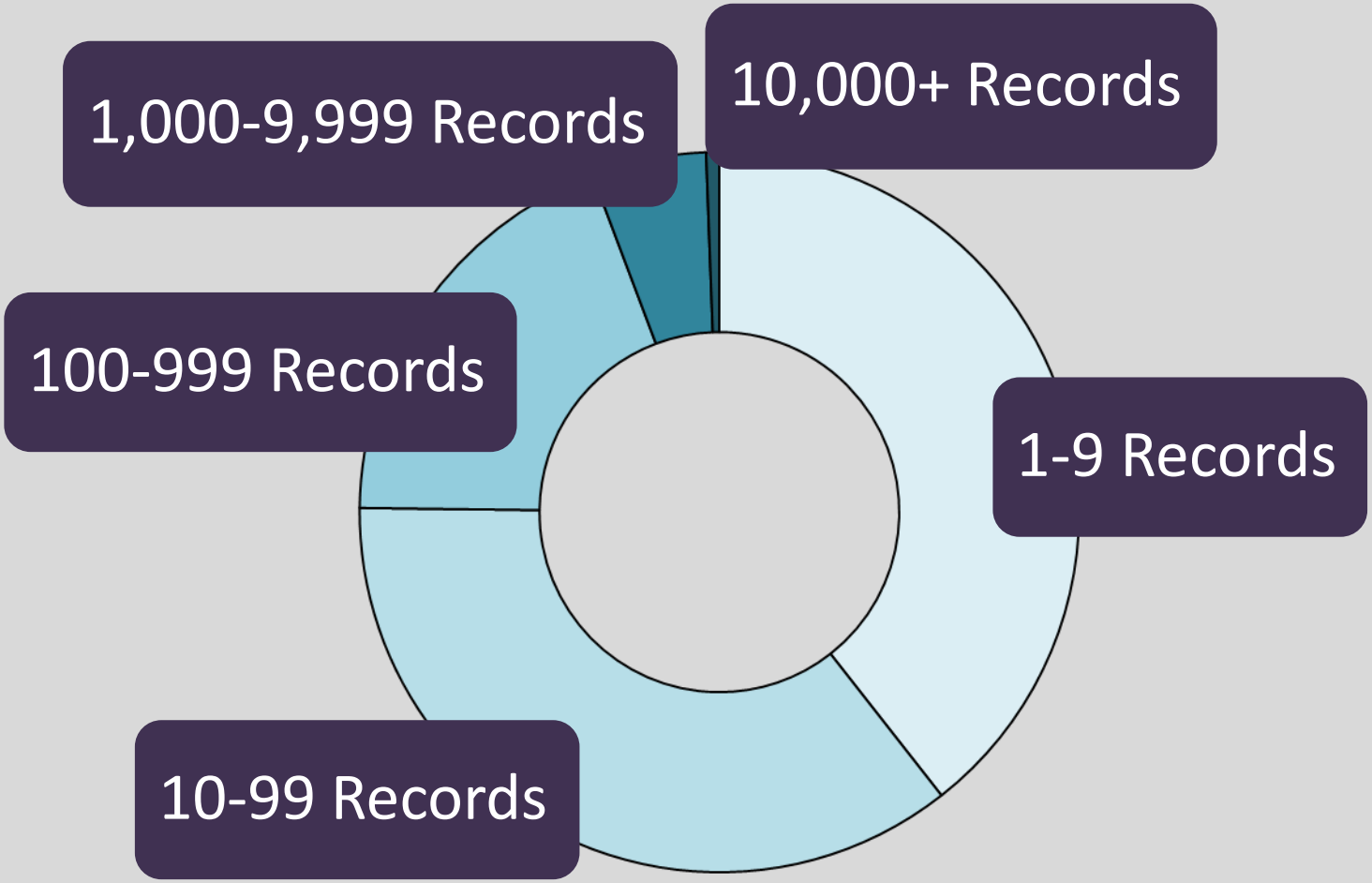
Compliance Date	Labeling and Data Submission	Direct Marking (reusable and reprocessed
September 24, 2014	• Class III devices • Devices licensed under the PHS Act	
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices	• LS/LS devices
September 24, 2016	• Class II devices	• Class III devices and devices licensed under the PHS Act
September 24, 2018	• Class I devices and unclassified devices**	• Class II devices
September 24, 2020		• Class I devices and unclassified devices**

Extended by enforcement discretion guidance

**The FDA issued guidance stating the agency intends not to enforce the class I/unclassified device compliance dates for two years (two year period ending September 24, 2020 for labeling and GUDID submissions; September 24, 2022 for direct marking).

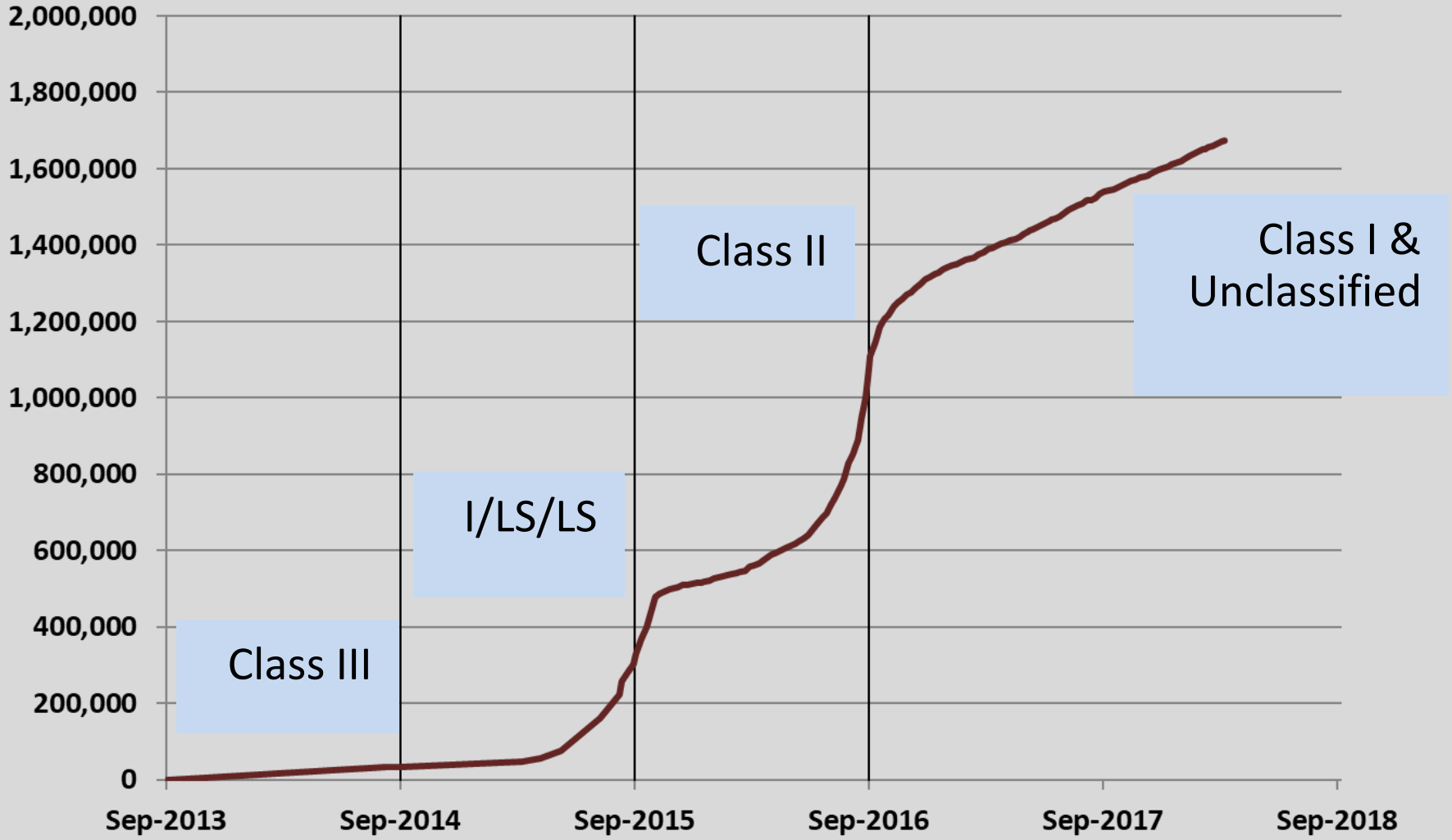
4,200+ Companies Have Published Records to GUDID

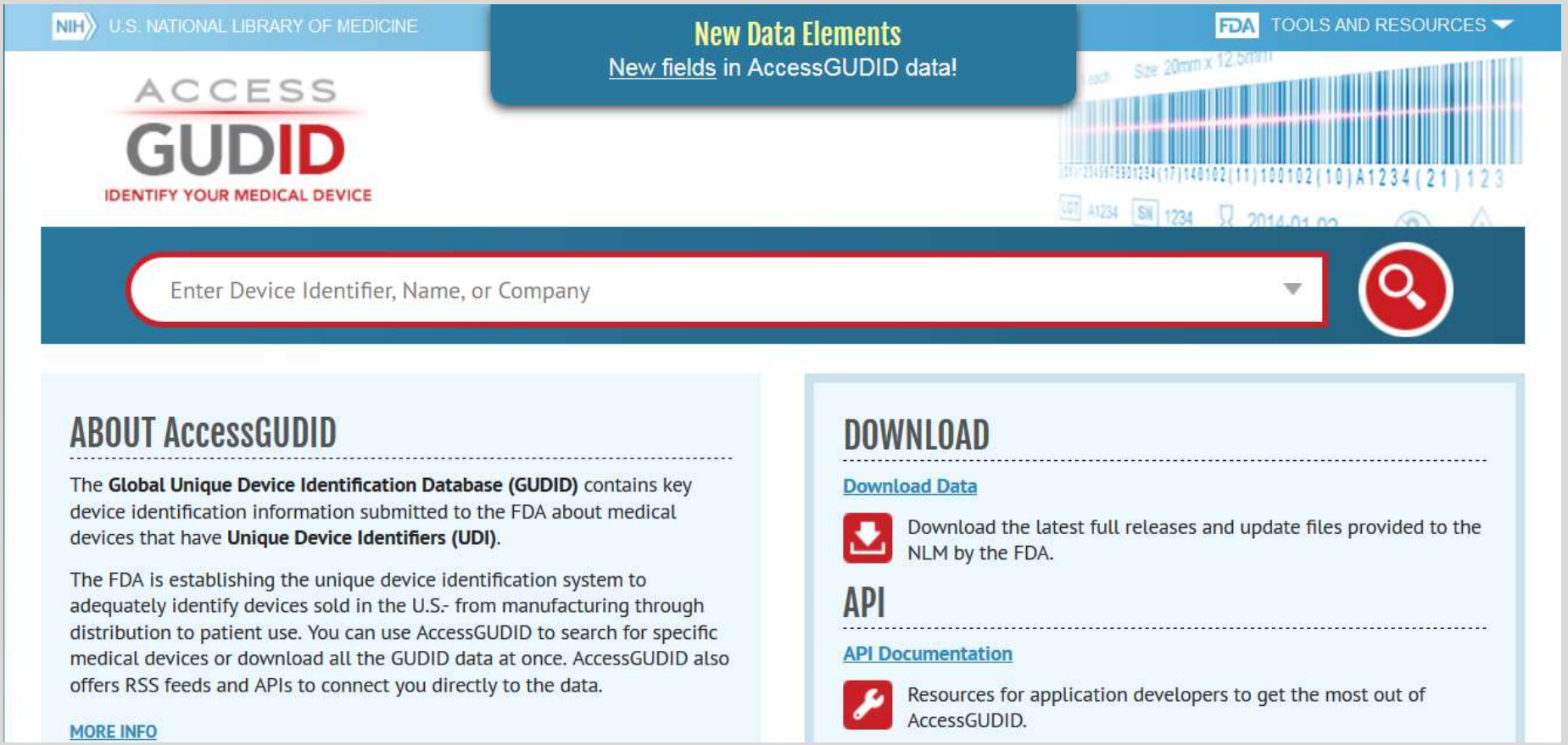
Data Current as of April 2, 2018



GUDID Records and Submission Compliance Deadlines

Data Current as of April 2, 2018





accessgudid.nlm.nih.gov

Key policy decisions issued through alternatives, letters to industry and guidance documents

Published Policy Decisions

Devices manufactured and labeled prior to the compliance date (Grandfather)

Class I and unclassified devices

Universal Product Code (UPC)

Direct mark requirements

Convenience Kits

Nonsterile implant trays

Devices manufactured and labeled prior to their compliance date (Grandfathered)

- 21 CFR 801.30(a)(1) – A device manufactured and labeled prior to its established compliance date is not required to bear a UDI on its label or to be directly marked until three years after that compliance date.

- For sterile class III, class II and I/LS/LS devices, alternative extends the period by two years (five years total). (Alternative UDI-A170001)

- Consigned and loaned devices (See Direct Marking Guidance)

Compliance Policy for Class I and Unclassified Devices

- Established compliance date for Class I and unclassified devices (other than I/LS/LS) is September 24, 2018 for labeling and data submission requirements, and September 24, 2020 for direct mark requirements.

- January 16, 2018, published IIE guidance outlining enforcement discretion for Class I and unclassified devices (other than I/LS/LS) to September 24, 2020 for labeling and data submission requirements, and September 24, 2022 for direct mark requirements.

  (Class I and Unclassified Guidance)

Universal Product Code (UPC)

- UDI requirements do not apply to Class I devices that are cGMP exempt
- Class I devices are not required include PIs in their UDIs
- For Class I devices, UPC on the device label and device package may be deemed to satisfy the requirements of 21 CFR 801.20
- For certain Class II and unclassified devices, alternatives were granted to apply the UPC exception above, for a limited time, to those devices principally sold at retail.(Alternative UDI-A160001 and UDI-A160002)

Direct Mark Requirements

- 21 CFR 801.45 requires direct mark on devices intended to be used more than once and intended to be reprocessed before each use.
- November 17, 2017, published Direct Marking Guidance:
  - Used more than once means used on more than one patient
  - Reprocessed means sterilization and/or high-level disinfection between uses
- Grandfather: three year period begins from labeling and data submission compliance date, not direct mark compliance date. Implementation Timeframe (Slide 14)

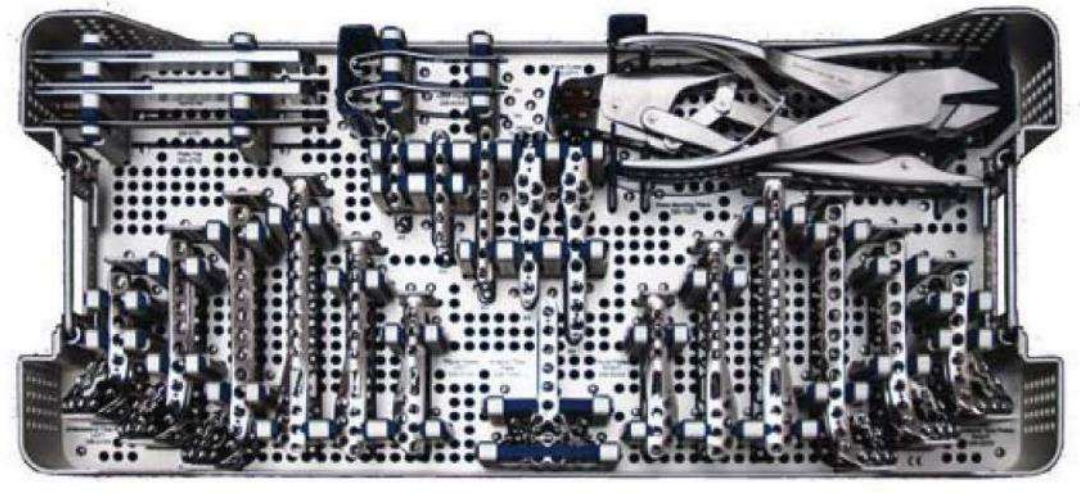
Convenience Kits

21 CFR 801.30(11) – if the immediate container of a convenience kit bears a UDI, the individual devices within the convenience kit are not required to bear UDIs.

“Convenience kit” defined as: two or more different medical devices packaged together for the convenience of the user.

Too broad to meet the objectives of the UDI program.

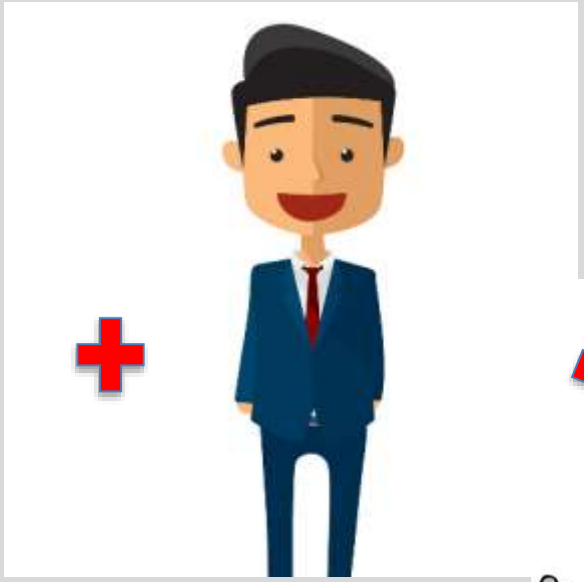
Example: Non-Sterile Implant Trays

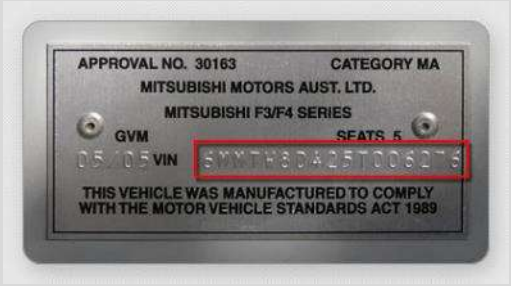


- Non-sterile orthopedic implants and instruments in a sterilization tray
- To ensure adequate options, many more implants are supplied in the tray than expected to be used in a single surgical procedure.
- Implants are selected and removed as needed. They are later replaced and the tray is sent for cleaning and sterilization between uses.
- To recognize this as a convenience kit, hinders the objectives of the UDI program.

UDI Is the Key to Health Care Data

Keys to Identification

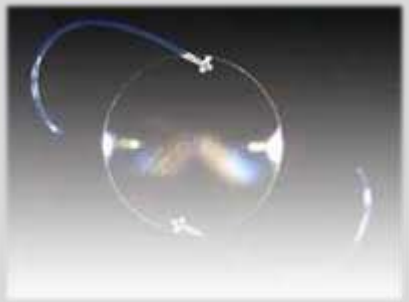


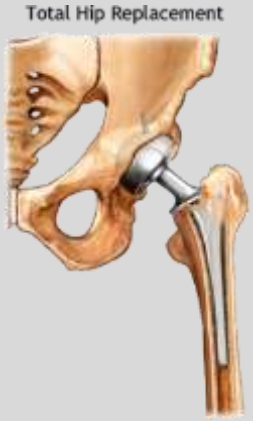


If there are Errors in VIN or SS#

Terrie's Mom

IOL
2006





HIP
2008

DES
2010

WALKER
2012

ICD
2011

If there are errors in UDI Data…

I don't worry about my devices. My doctors take care of me. They'll let me know if there is a problem..

Recalls

Adverse Events

Device Registries

Annual Reports

Claims

UDI Education Resources

- Unique Device Identification (UDI) System Regulatory Overview Presentation [17 minute video on requirements]
- The GUDID Device Identifier (DI) Record Presentation [26 minute video on records]
- Global Unique Device Identification Database (GUDID) Account Request: Preparation and Process Presentation [18 minute video on preparing for submission]
- FDA UDI Help Desk

No Man is an Island

Questions

Please evaluate this session:

surveymonkey.com/r/DEV-D2S06

Your Call to Action

- Make 2018 the Year of GUDID Data Quality!
- Validate your UDI
- Review and make necessary corrections for existing DI records
- For new DI records establish procedures to review records during the DI record grace period


FDA
U.S. FOOD & DRUG
ADMINISTRATION