

# Unique Device Identification: Building Block for the National Evaluation System

*Clearly identifying a device as part of  
real-world evidence*

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Engineering

Senior Advisor for UDI Adoption



# What is UDI?

- Regulation
- Requirements on Label
- Submission to Global Unique Device Identification Database (GUDID)



(01)04022495770332(17)200731(10)0061443956



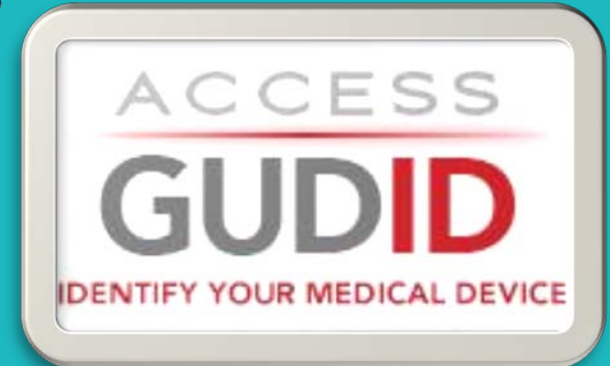
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**[accessgudid.nlm.nih.gov](https://accessgudid.nlm.nih.gov)**



# **2010** What is UDI ?

## **Medical Procedures**<sup>1</sup>

**1,000,000 Cardiac Catheterizations**  
**719,000 Total Knee Arthroplasties**  
**332,000 Total Hip Replacements**

## **New Cars Sold**<sup>2</sup>

**1,230,500 Hondas**  
**908,600 Nissans**  
**358,500 Volkswagens**

<sup>1</sup> Source: CDC/NCHS National Hospital Discharge Survey, 2010

<sup>2</sup> Source: WardsAuto - 2010 New Vehicle Sales

# 2007 What is UDI?

## Unique Device Identification System

“The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through direct or indirect use, and may include information on the lot or serial number.”

**-added to the FD&C Act by section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Public Law 110-85.**

# 2016 What is UDI?



**U.S. Food and Drug Administration**  
Protecting and Promoting *Your Health*

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## Medical Devices

[Home](#) > [Medical Devices](#) > [Device Advice: Comprehensive Regulatory Assistance](#) > [Unique Device Identification](#) > [UDI Resources](#)

### UDI Resources

#### Resources for You

- [FDA UDI Help Desk](#)
- [AccessGUDID](#)

## UDI Resources

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This page contains links to more information on Unique Device Identification System-related rules, guidances, training, and communications.

### UDI Rule and Guidances

- [The Enforcement Policy for National Health Related Item Code and National Drug Code Numbers Assigned to Devices - Draft Guidance for Industry and Food and Drug Administration Staff, February 3, 2016 \(PDF - 177KB\)](#)
- [Unique Device Identification: Convenience Kits - Draft Guidance for Industry and Food and Drug](#)

[www.FDA.GOV/UDI](http://www.FDA.GOV/UDI)

# UDI = Device Identifier (DI) + Production Identifiers (PI)

Unique Device Identifier (**UDI**) – *globally unique in accordance with ISO standards*

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*

Production Identifier (**PI**) – *a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:*

- lot or batch within which a device was manufactured;
- serial number of a specific device;
- expiration date of a specific device;
- manufacturing date
- distinct identification code

# What is UDI?

1<sup>st</sup> requirement ...*the label of every medical device shall bear a unique device identifier (UDI)...*

2<sup>nd</sup> requirement...*the labeler of a device must provide the information required ... for each model or version required to bear a unique device identifier (UDI)...*



(01)040224957703



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520,000+

ACCESS

GUDID

IDENTIFY YOUR MEDICAL DEVICE



\*X990123ABC0/5\$31005151234AB/S5678EDFG/16D20151001J\*

[accessgudid.nlm.nih.gov](http://accessgudid.nlm.nih.gov)



# Why is Unique Device Identification Important?

*What you see and hear depends a good deal on where you are standing; it also depends on what kind of a person you are.*

*~C.S. Lewis*





# The Washington Post

By tracking device IDs, like the vehicle identification numbers on cars, regulators could spot patients across the country coming into an emergency room or developing infections after a procedure. [1/31/16](#)

## Modern Healthcare

Experts hope the identifiers will help providers reduce costs with more efficient medical-supply management, and improve patient safety with better reporting and tracking of faulty products and adverse events. [9/25/15](#)

# UDI is important to...

## **PATIENTS**

Care Providers

Manufacturers

Healthcare supply chain / inventory management

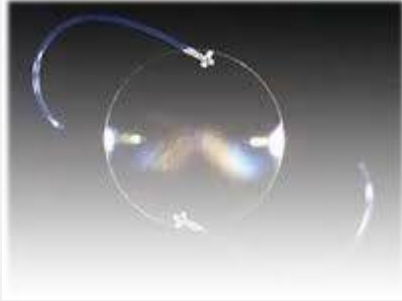
Researchers

Data Analysts

**National Medical Device Evaluation System**

# First Focus: Implants

**IOL**  
**2006**

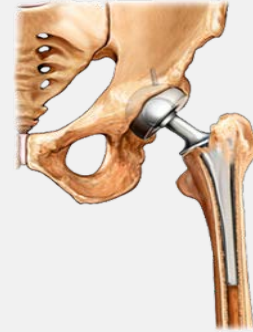


**DRUG ELUTING STENT**  
**2010**

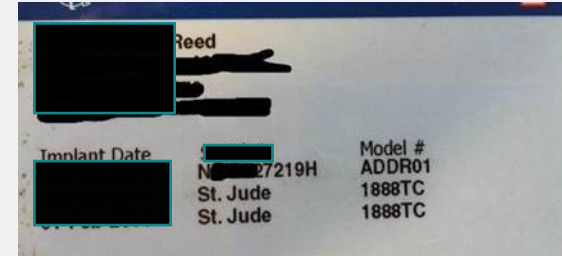


**WALKER**  
**2012**

Total Hip Replacement



**HIP**  
**2008**



**PACEMAKER**  
**2011<sup>1</sup>**

# Patient Expectations

Recalls

De  
Registries

Evaluation  
Gap




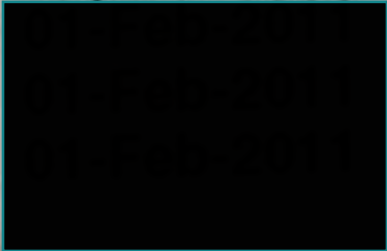

Adverse

I don't worry about my implants. My doctors take care of me and would let me know if there is a problem.

ns



# Current Implant Information

		
Implant Date	Serial #	Model #
	 9H	ADDR01
	St. Jude	1888TC
	St. Jude	1888TC

# Device Identifier => Standard Data

The screenshot shows the ACCESS GUDID website interface. At the top, there's a teal banner with the text "Device Identifier => Standard Data". Below this, the website header includes the "ACCESS GUDID" logo with the tagline "IDENTIFY YOUR MEDICAL DEVICE". A red button prompts users to "Contact us with your comments and suggestions for the site." On the right, there's a barcode and some technical specifications like "Qty 1 each" and "Size 20mm x 12.5mm". A search bar contains the text "1888TC". Below the search bar, a blue navigation bar contains links for "HOME", "ABOUT", "NEWS", "API", "DOWNLOAD", and "HELP". A teal arrow points from the search bar to a highlighted box containing the text "DEVICE: Tendril™ (05414734501743)". Below this, the page shows a section for "VIEW ALL SECTIONS | CLOSE ALL SECTIONS" followed by a collapsed section titled "DEVICE IDENTIFIER (DI) INFORMATION". This section contains details about the device: Brand Name (Tendril™), Version or Model (ST), Catalog Number (1888TC-46), Company Name (ST. JUDE MEDICAL, INC.), and Device Description (No description). To the right of these details, it shows the Primary DI Number (05414734501743), Issuing Agency (GS1), and Device Count (1). Below the device information, there are links for "CLOSE", "DEVICE CHARACTERISTICS", "DEVICE STATUS", "ALTERNATIVE AND ADDITIONAL IDENTIFIERS", and "CUSTOMER CONTACT [?]".

ACCESS  
**GUDID**  
IDENTIFY YOUR MEDICAL DEVICE

Contact us with your comments and suggestions for the site.

Qty 1 each Size 20mm x 12.5mm

1888TC

HOME ABOUT NEWS API DOWNLOAD HELP

DEVICE: Tendril™ (05414734501743)

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

− DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Tendril™  
Version or Model: ST  
Catalog Number: 1888TC-46  
Company Name: ST. JUDE MEDICAL, INC.  
Device Description: No description.

Primary DI Number: 05414734501743  
Issuing Agency: GS1  
Device Count: 1

CLOSE

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

## Link Patient to Device Identifier

MR # 000000000000

### Active Implantable Device List

DI Lot Serial Expiration Mfr Date DIC	Description (GMDN or SNOMED)	Company Name	Brand Name	Model	MRI Safe	Labeled as containing latex
05414734501743 Lot: 123456 Exp:12/31/2025	Endocardial pacing lead	St. Jude Medical Inc.	Tendril™	ST	Labeling does not contain MRI Safety Information	No



# UDI is important to the....

## National Medical Device Evaluation System

### UDI is the Link between patient and device that can improve:

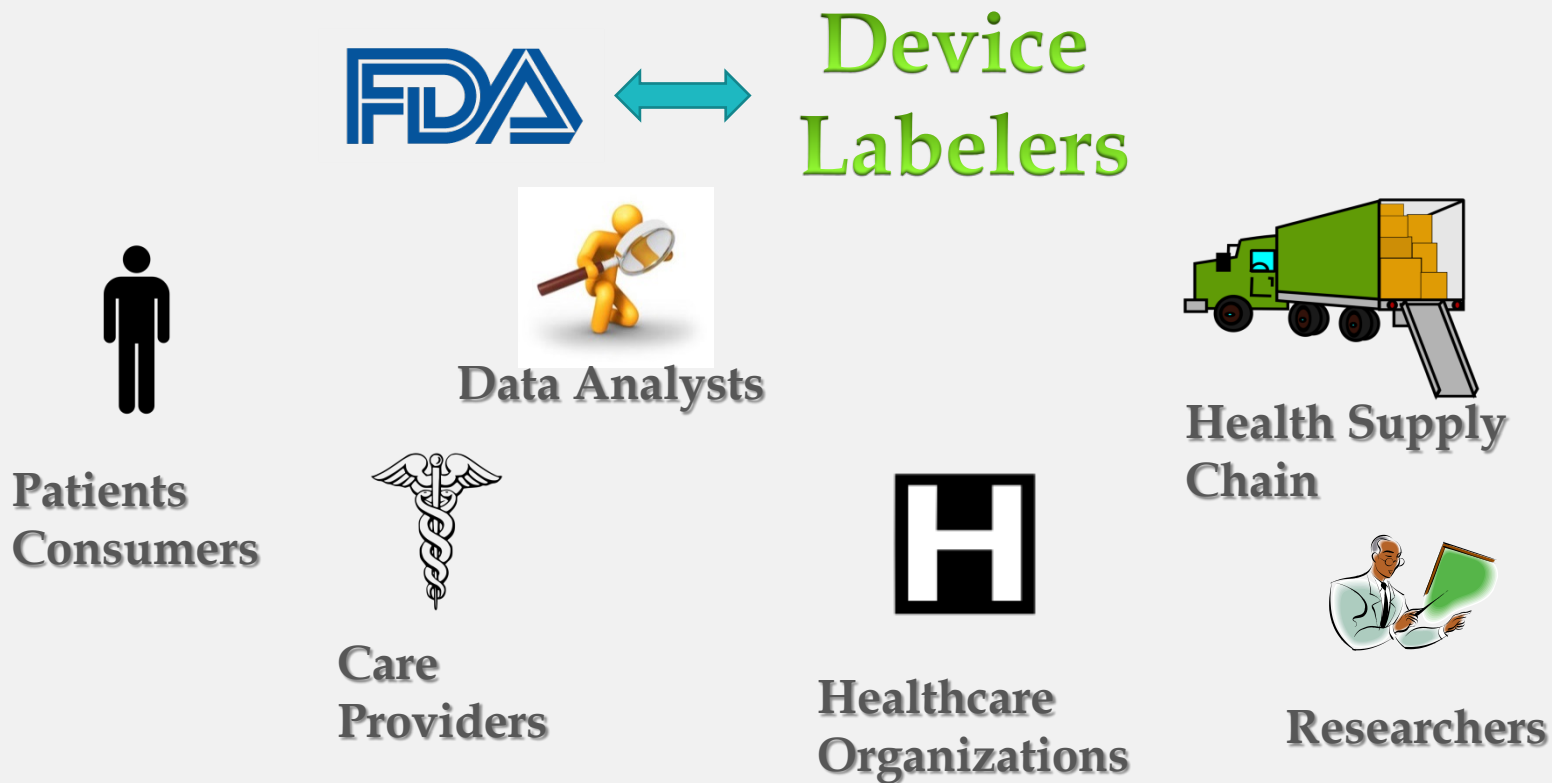
- Ability to detect and respond to safety issues – active and reported
- Efficiency to manage device recalls and remove harmful product
- Understanding of device characteristics to reduce medical errors
- Precision in studying devices in diverse populations and better understand how devices behave in the real world

# Developing a Learning UDI Community

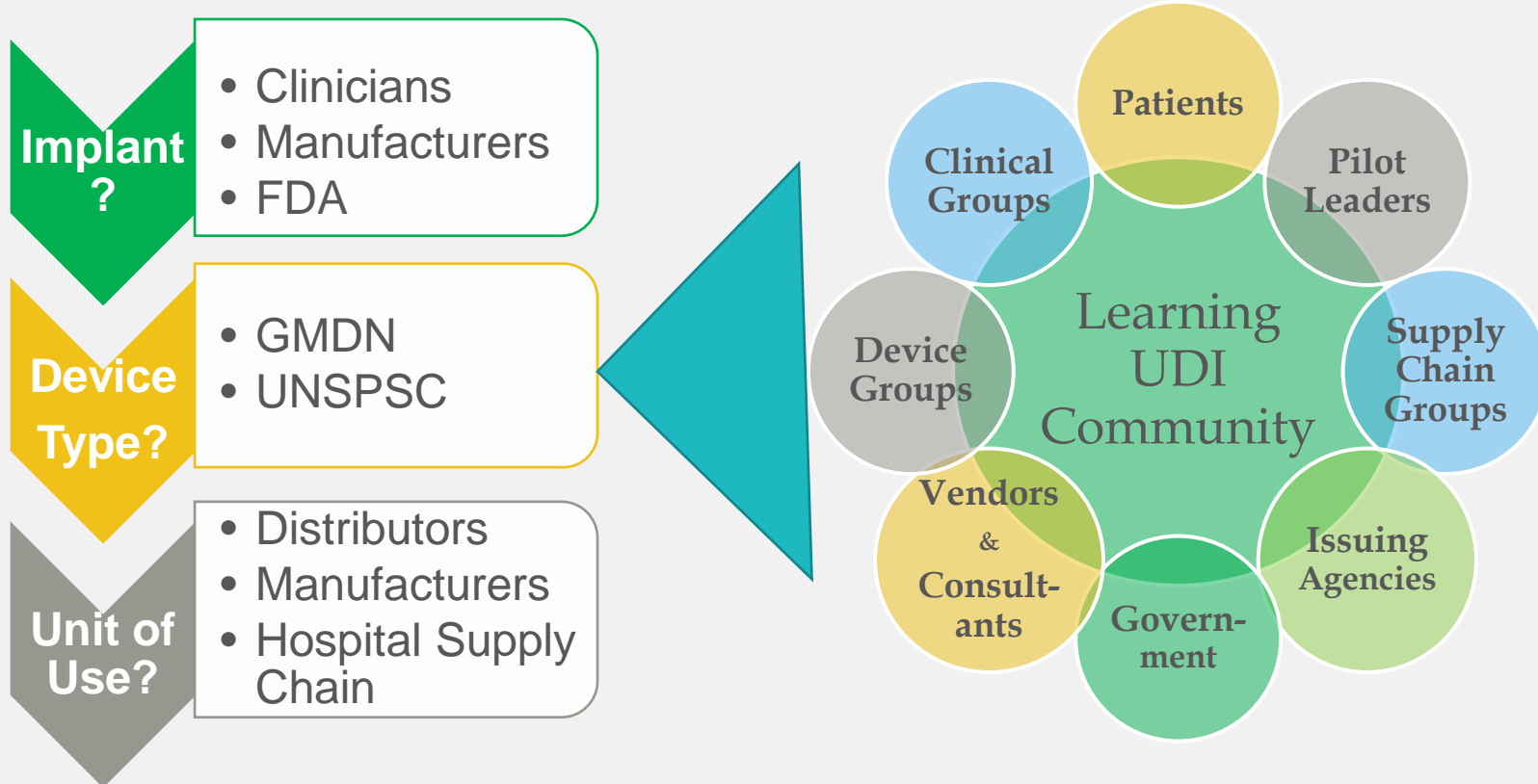
*How wonderful it is that nobody need  
wait a single moment before starting to  
improve the world. ~Anne Frank*



# Building a Community to Ensure UDI Adoption



# Learn More at the UDI Roundtable



Thank you!