Unique Device Identification (UDI)-Key to Interoperability

Behnaz Minaei
Center for Devices and Radiological Health (CDRH)
US Food and Drug Administration (FDA)
May 5, 2017

What is a UDI?

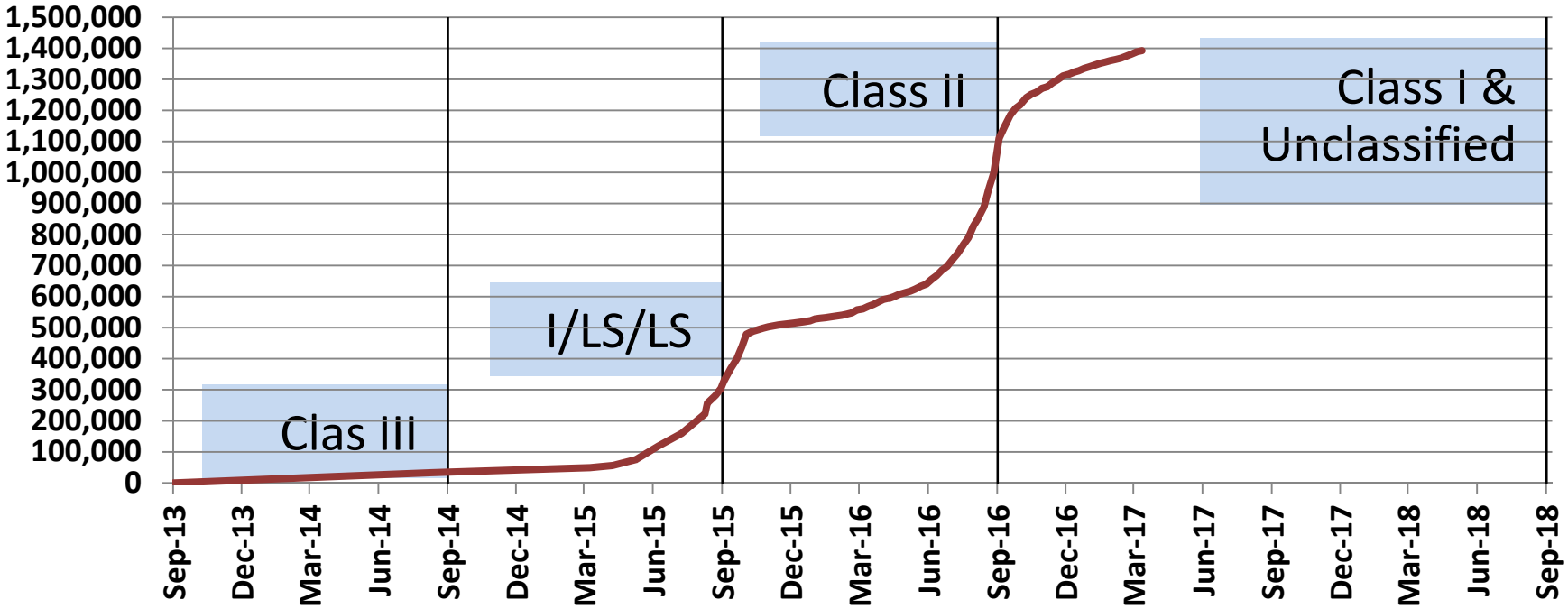
Required on the device label, packages or, in some cases, on the device itself
(in plain text and machine readable format (AIDC))

The labeler of a device must provide the information required for each model or version

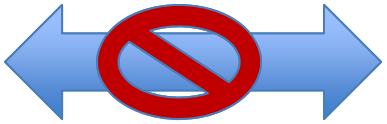
ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

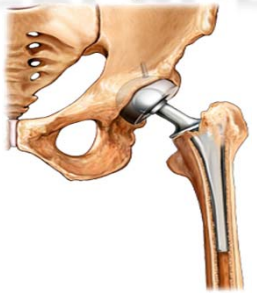
GUDID Records and Submission Compliance Deadlines

*Data Current as of **April 3, 2017***



2005 HIP REPLACEMENT





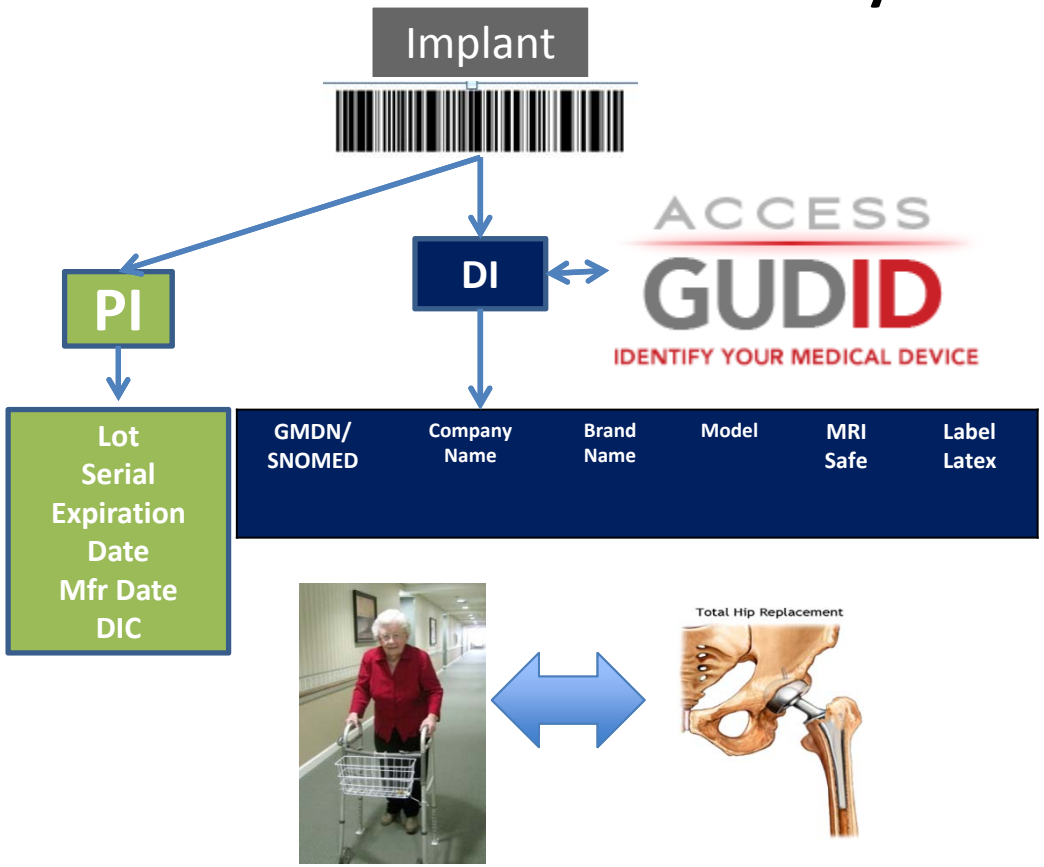
Patient

- Who made it?
- What brand it is?
- What model?
- Has it been recalled?
- Impact on other care?

Population

- Did it hasten other conditions?
- What was expected life of the device?
- Did it last longer than that?
- How to analyze UDI data to support innovation?

2015 Edition §170.315(a)(14) Implantable Device List
January 2018



Certified Health IT Product List

Edition	Developer	Product
2015	Epic Systems Corporation	EpicCare Inpatient EHR Suite
2015	MEDHOST	MEDHOST Enterprise
2015	Netsmart Technologies	myAvatar Certified Edition
2015	Allscripts	Sunrise Acute Care
2015	Allscripts	Sunrise Ambulatory Care
2015	Medical Transcription Billing Corporation (MTBC)	TalkEHR
2015	Evident	Thrive EHR
2015	Evident	Thrive Provider EHR

As of 4/5/2017

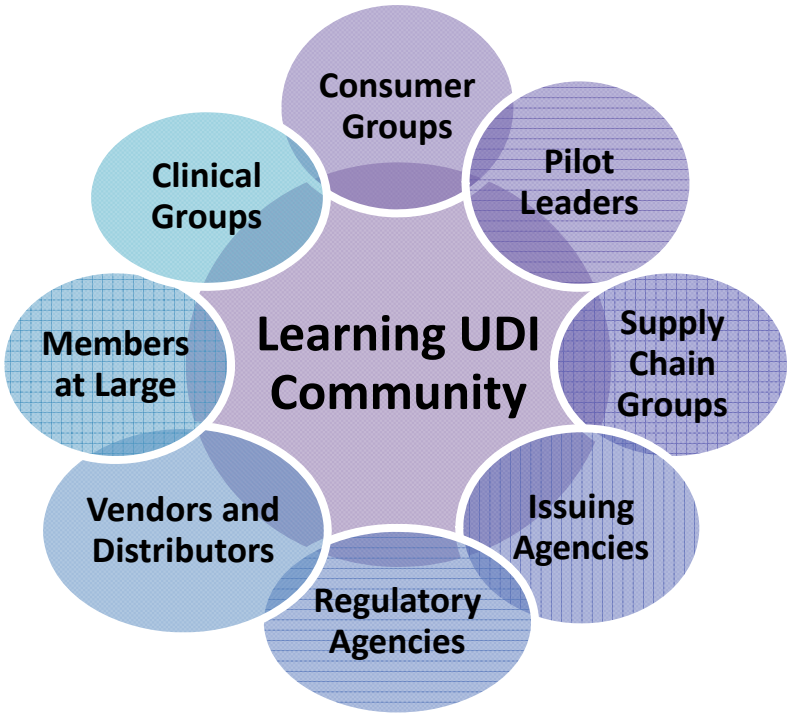
2017 – Realizing UDI Value

Goal: UDI in data sources of acceptable data quality such that it realizes public health and economic return on investment across the device ecosystem

Demonstrate and improve value through device initiatives such as:

- **Medical Device Innovation Consortium (MDIC) National Evaluation System for health Technology (NEST)**
- **Medical Device Epidemiology Network (MDEpiNET)**
- MDIC Case for Quality (CFQ) – dashboards for purchase decisions
- Association for Healthcare Resources and Materials Management (AHRMM) Learning UDI Community (LUC)
- International Medical Device Regulators Forum **(IMDRF)**

AHRMM LUC
Learning UDI Community



- Major Objectives:
  - Identify UDI adoption hurdles
  - Identify UDI adoption solutions
  - Host in the LUC Resource Center

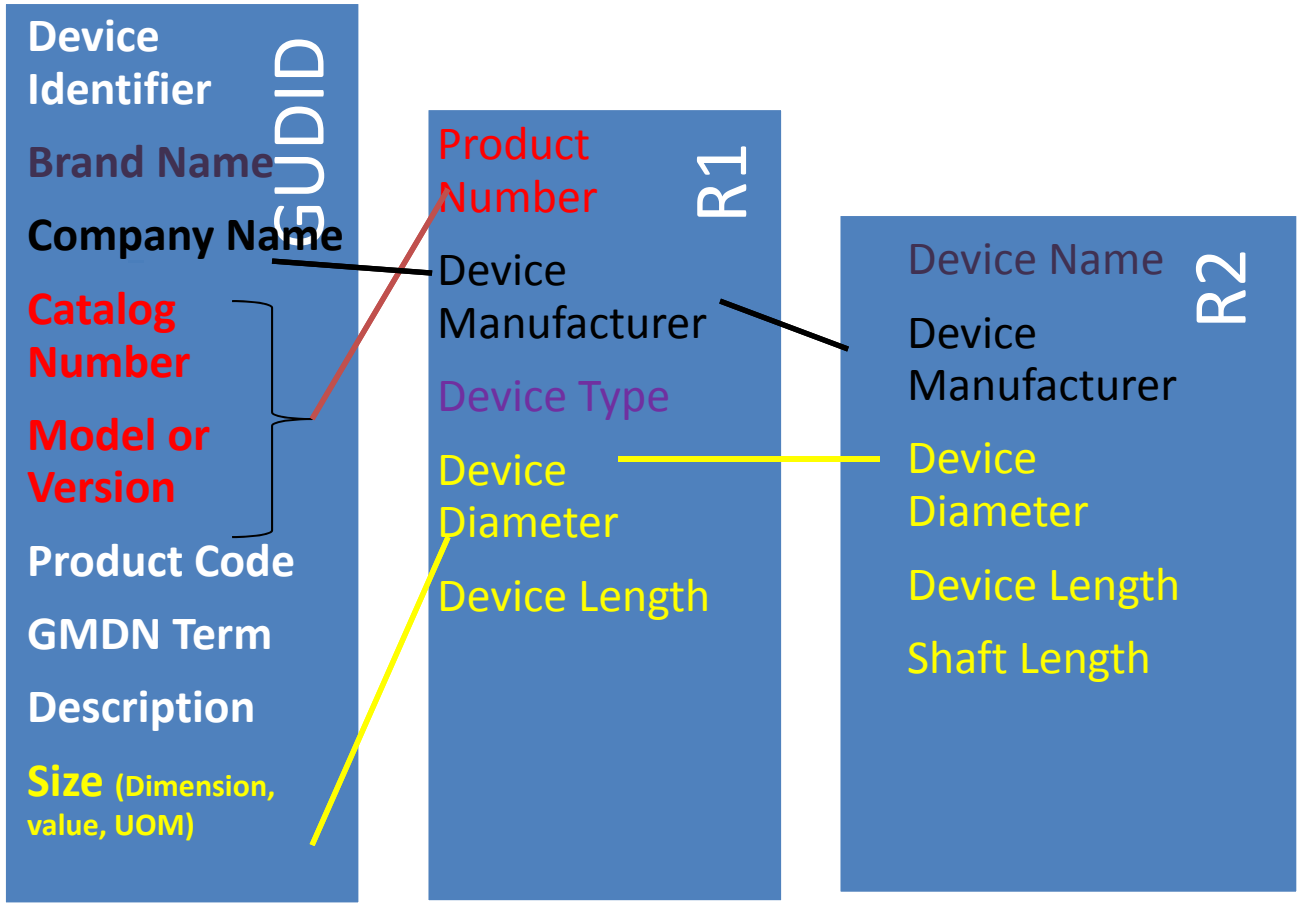
International Medical Device Regulatory Forum

2013 – UDI principles and attributes created by IMDRF

IMDRF code	Document title
IMDRF/REGISTRY WG/N33 FINAL:2016	Principles of International System of Registries Linked to Other Data Sources and Tools - PDF (873kb) Principles of International System of Registries Linked to Other Data Sources and Tools - DOCX (203kb)
IMDRF/RPS WG/N19 FINAL:2016	Common Data Elements for Medical Device Identification - PDF (747kb) Common Data Elements for Medical Device Identification - DOCX (135kb)

2017 - New EU MDR Regulations Approved. Time to revisit Global implementation of UDI

Comparison of 3 Data Sources



Analysis of One Record

GUDID		Registry 1		Registry 2	
Field Name	Field Value	Field Name	Field Value	Filed Name	Field Value
Device Identifier	08714729805885				
Brand Name	**Epic™ Vascular**	Device Type	**Epic Vascular Self Expanding Stent (120 CM shaft)**	Device Name	**Epic Vascular Stent System 9.0 mm x 100 mm**
Company Name	**BOSTON SCIENTIFIC CORPORATI**	Device Manufacturer	**Boston Scientific**	Device Manufacturer	**Boston Scientific Corporation**
Catalog Num.	H749**39200091020**	Product Num.	**39200-09102**		
Model or Version	H74939200091020				

GUDID as Source of Truth

DI Record can be used to auto-populate EHRs, Registries etc

WL GORE

DEVICE: GORE VIABAHN Endoprosthesis (00733132614387)

DOWNLOAD: XML

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: GORE VIABAHN Endoprosthesis
Version or Model: VBC050202
Catalog Number:
Company Name: W. L. Gore & Associates, Inc.
Device Description: No description.

Primary DI Numbe: 00733132614387
Issuing Agency: GS1
Device Count: 1

Vascular Quality Initiative

Treatment Type: Stent Graft
Product Number or DI: VBC
Manufacturer
Type
GUDID Diameter
GUDID Length

VBC050202 DI:
VBC050502 DI:00733132614394
VBC051002 DI:
VBC051502 DI:00733132614417
VBC060202 DI:00733132614424
VBC060501 DI:00733132614431
VBC060502 DI:00733132614448

Device 1

Treatment Type: Stent Graft
Product Number or DI: VBC050502 DI:00733132614394
Manufacturer: W. L. Gore & Associates, Inc.
Type: GORE VIABAHN Endoprosthesis
GUDID Diameter: 5 Millimeter
GUDID Length: 5 Centimeter

What Can you Do?

Assessing the quality and consistency of data requires data standards.

Be guided by common sense and pragmatism
To benefit patient care