The Global Language of Business

Medical Device Identification and Data Management

GS1 Healthcare Conference, Berlin

5 April 2017

Panelists

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Auto-ID Affairs

The Global Language of Business

Unique Device Identification (UDI)
US FDA Center for Devices and Regulatory Health

Regulatory Overview
UDI as a Healthcare Standard

Linda Sigg, Associate Director, Informatics
Terrie Reed, Senior Advisor for UDI Adoption
April 5, 2017

UDI Rule – September 2013

- FDAAA 2007 and FDASIA 2012
- Objectives of UDI Program:

Establish a system to adequately identify devices through distribution and use

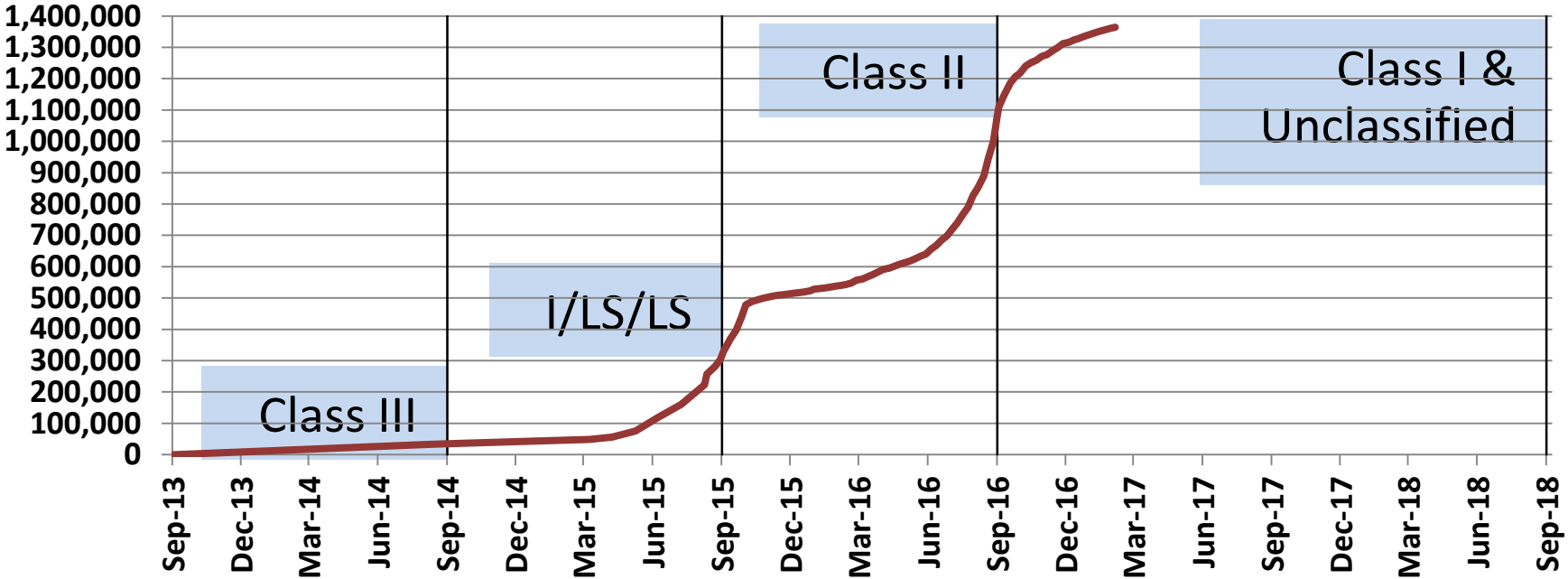
- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, and registries

UDI Compliance Dates

Compliance Date	Must bear a UDI & submit data to GUDID
September 24, 2014	• Class III devices, incl. class III stand alone software • Devices licensed under the PHS Act
September 24, 2015	• Implantable, life-supporting and life-sustaining (I/LS/LS) devices, incl. stand alone software • *Direct Marking of I/LS/LS for certain intended uses*
September 24, 2016	• Class II devices • *Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses*
September 24, 2018	• Class I devices and devices not classified class I, II or III • *Direct Marking of class II devices for certain intended uses*
September 24, 2020	• *Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses*

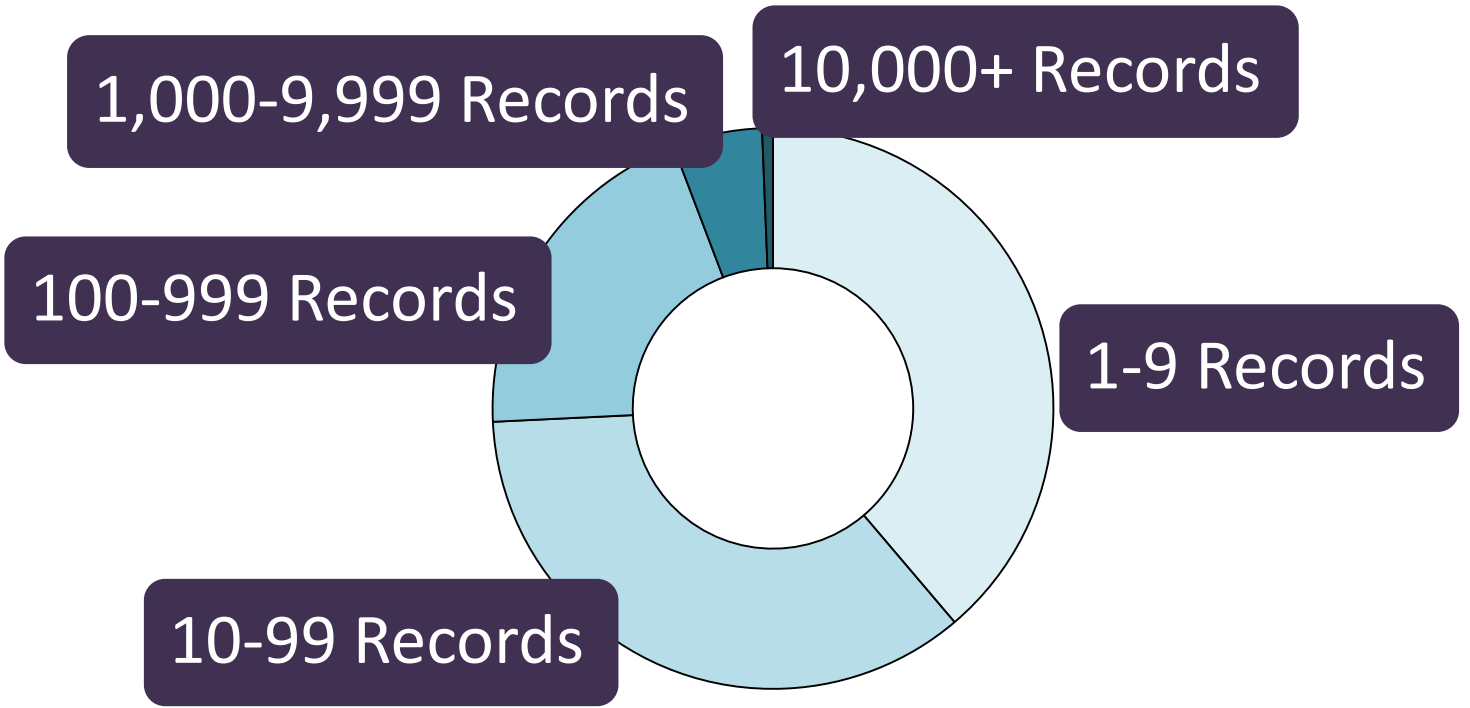
GUDID Records and Submission Compliance Deadlines

Data Current as of March 1, 2017



3,500+ Companies Have Published Records to GUDID

Data Current as of March 1, 2017

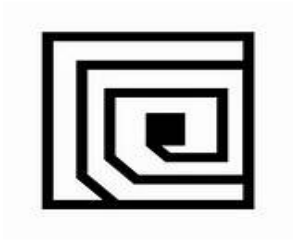


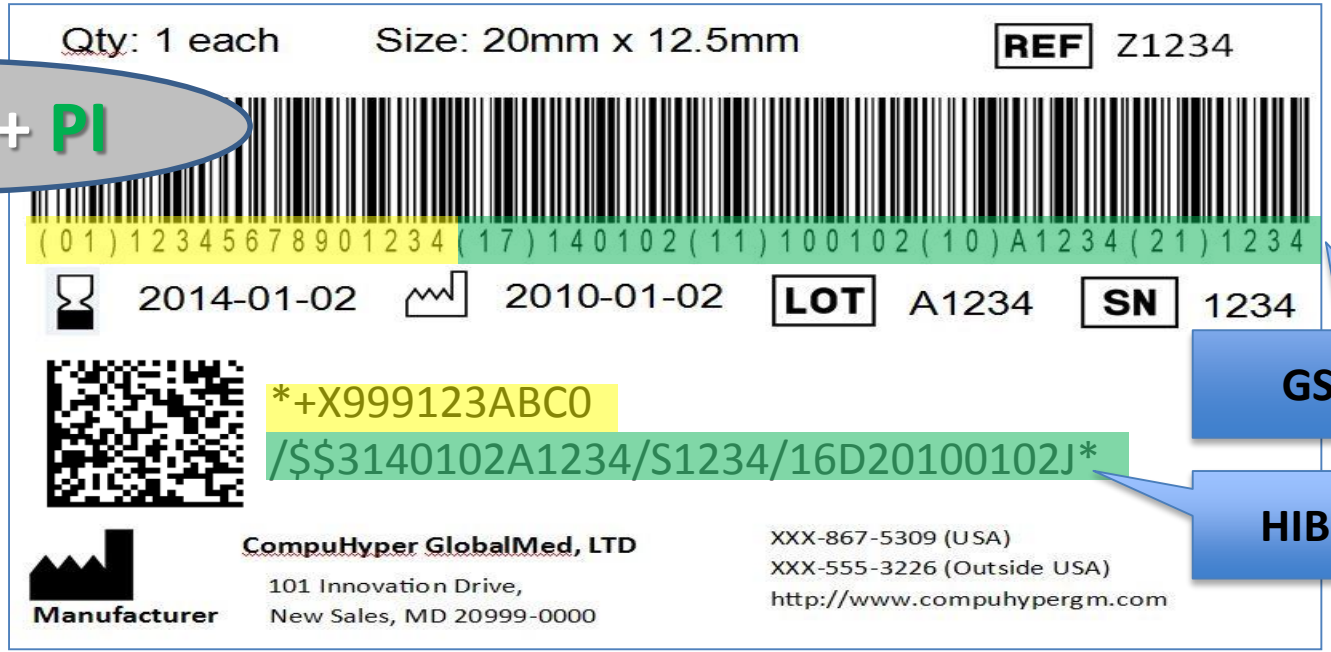
What is a UDI?

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

Code in plain text and machine readable format (AIDC)

UDI = DI + PI





Establish a UDI Program

- 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

UDI as a Healthcare Standard

Support for Master Data

Measuring Performance

Medical Procedures [1]

719,000 Total Knee Replacements

332,000 Total Hip Replacements

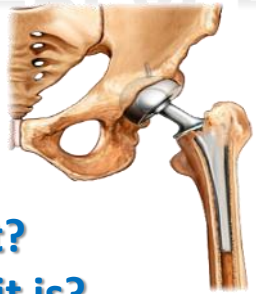
New Cars Sold [2]

1,230,500 Hondas

[1] Source: CDC/NCHS National Hospital Discharge Survey, 2010

[2] Source: WardsAuto - 2010 New Vehicle Sales

2005 HIP REPLACEMENT



Patient

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

Population

- What are common problems?
- Is pain normal?
- Did it hasten arthritis?
- What was expected life of device?
- Did it last longer than that?

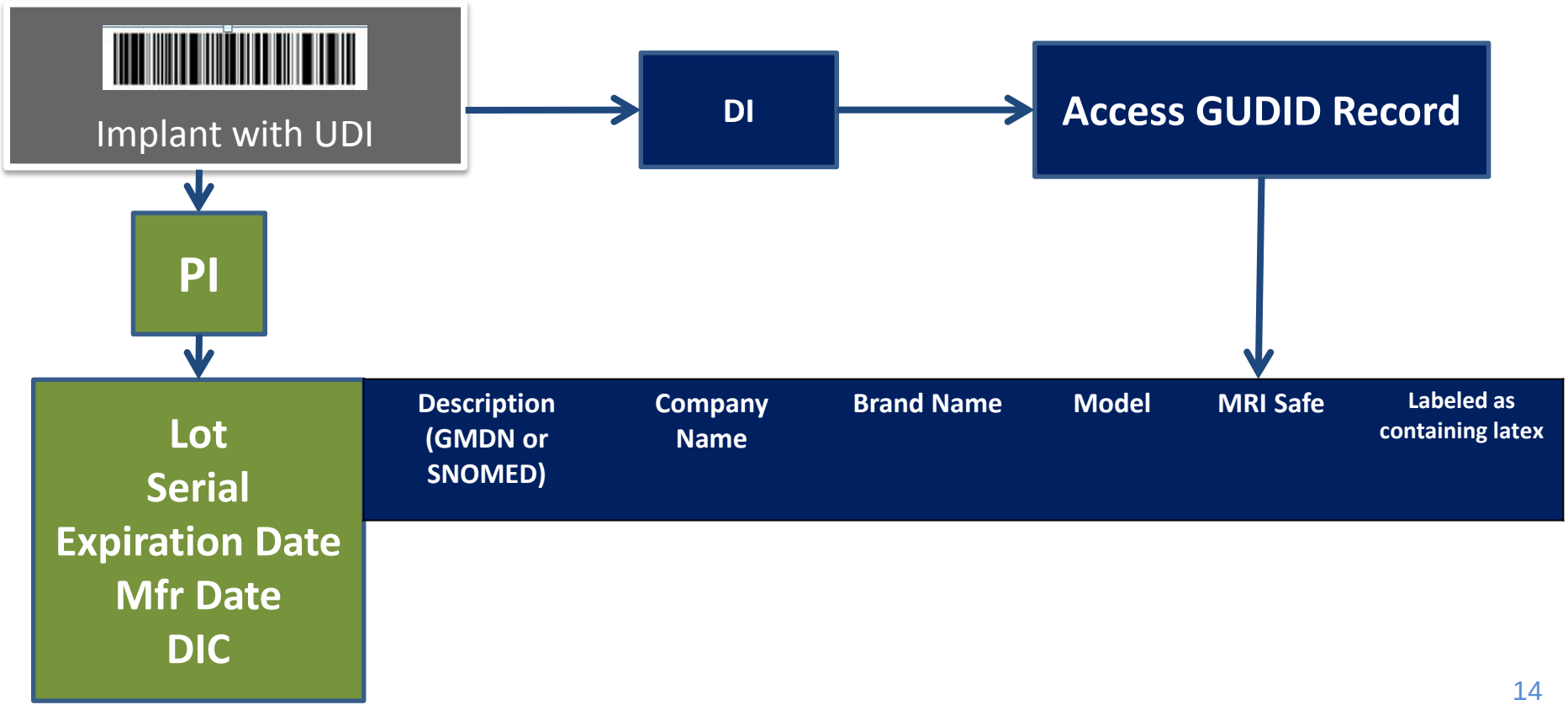
Healthcare Milestones and Drivers

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

UDI in Common Clinical Data Set

January 2018 – Transmit Implantable Device list for Patient

ONC Certification Criteria



Link Patient to Device Identifier

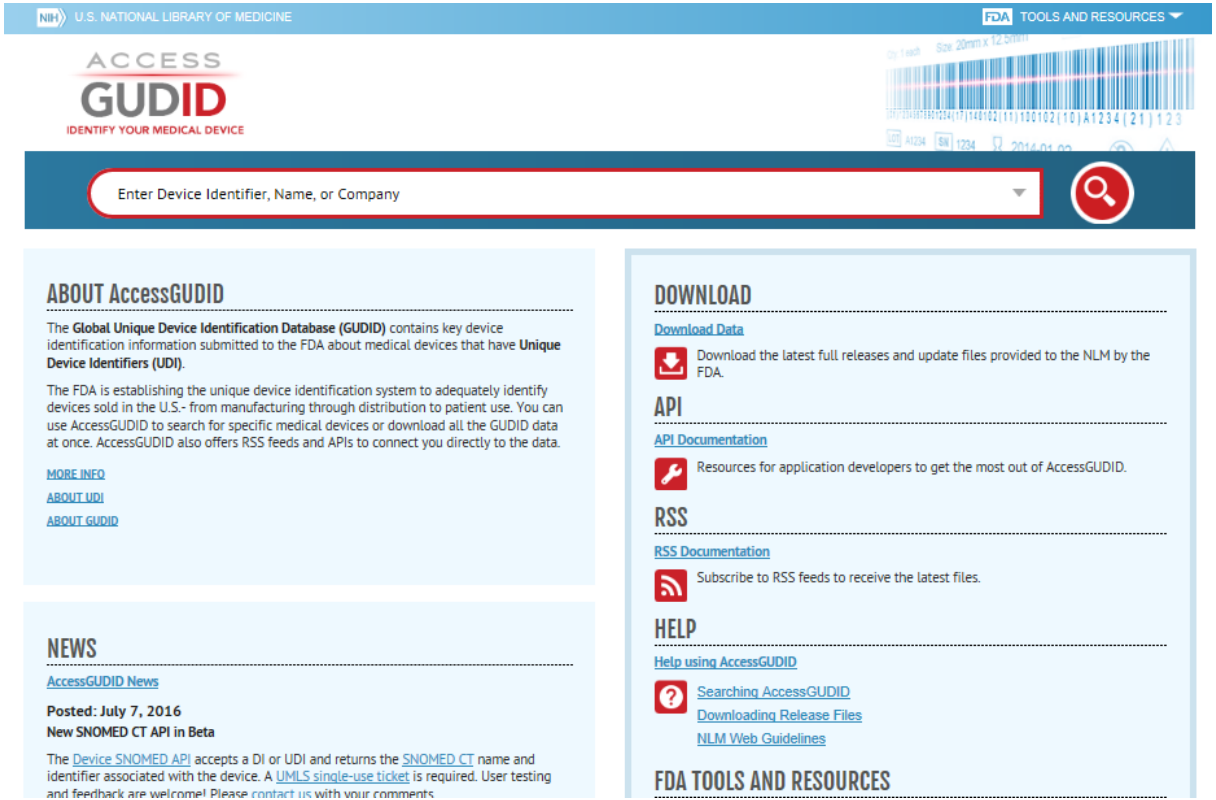
BABY MR # 00000000000

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
00801741051746 Lot: 123456 Exp:12/31/2025	Central Venous Catheter	Bard Access Systems, Inc	Hickman 9F Pediatric Dual Lumen CV Catheter	0600320	Labeling does not contain MRI Safety Information	No

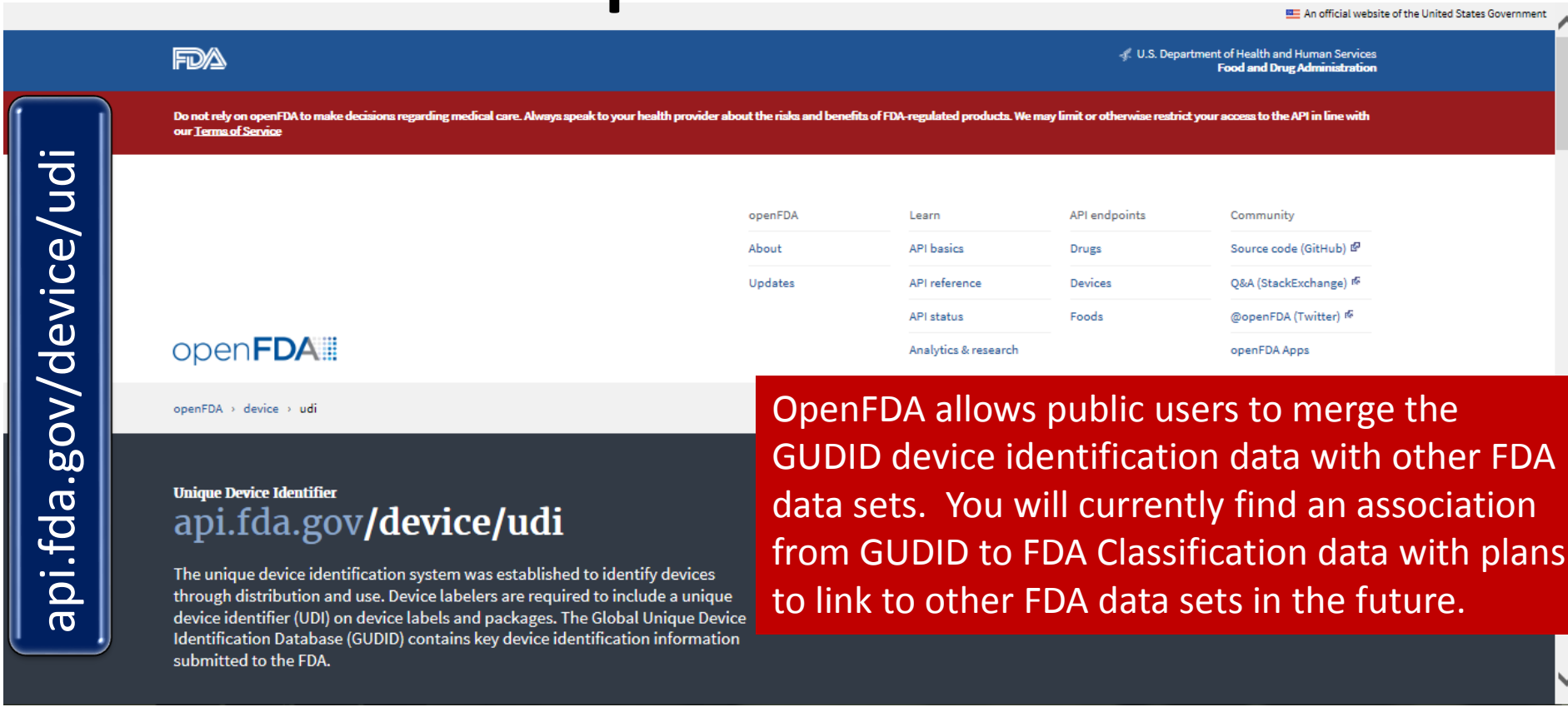
Access to Device Identifier (DI) Records AccessGUDID

Accessgudid.nlm.nih.gov



Access to Device Identifier (DI) Records OpenFDA

api.fda.gov/device/udi



OpenFDA allows public users to merge the GUDID device identification data with other FDA data sets. You will currently find an association from GUDID to FDA Classification data with plans to link to other FDA data sets in the future.

UDI and Device Initiatives

Collaboration and coordination across device initiatives is necessary to realize UDI system value

- ***FDA CDRH*** *UDI Team (Informatics team)*
- ***Medical Device Innovation Consortium*** *(MDIC) National Evaluation System for health Technology*
- **FDA CDRH** Medical Product Safety Network (MedSun)
- Medical Device Epidemiology Network (MDEpiNET)
- **MDIC** Case for Quality (CFQ)
- **Association for Healthcare Resources and Materials Management** (AHRMM) Learning UDI Community (LUC)
- International Medical Device Regulators Forum (IMDRF)

FDA CDRH Informatics Team

- Implement and support UDI rule
- Analyze GUDID data quality
- Work with Standards Development Organizations
- Update UDI system to meet stakeholder needs
  - Support and educate
  - Resolve complex issues
  - Test and use UDI as master data
  - Best practices and tools

Standards Development Work

Implanted Devices

Create/Update HL7 standards to fully support ONC and CMS requirements for **Implantable Device Lists**

- Domain Analysis Model (DAM) for UDI
- Implementation Guide (IG) for Consolidated-Clinical Document Architecture (HL7 C-CDA)
- UDI in the HL7 FHIR device resource and profiles to **extract from EHR to other sources**

Standards Development Work

Networked Devices

US Veteran's Health Administration, Integrating the Healthcare Enterprise, ISO, IEEE, network providers, manufacturers are exploring the value of UDI and data in GUDID as standard device identifier for purposes of:

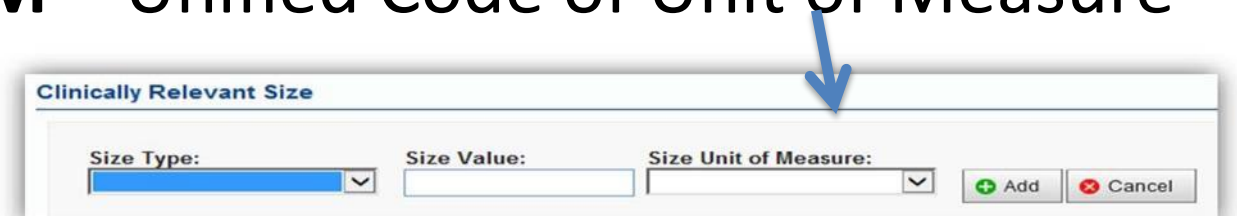
- Cybersecurity authentication
- ICD monitoring (IHE IDCO)
- Personal Health Device identification (IHE PHD)
- Point of Care device identification (IHE PCD)
- Standardizing device outputs (ISO 11073)

Data Standards in GUDID

- **GMDN** – Global Medical Device Nomenclature

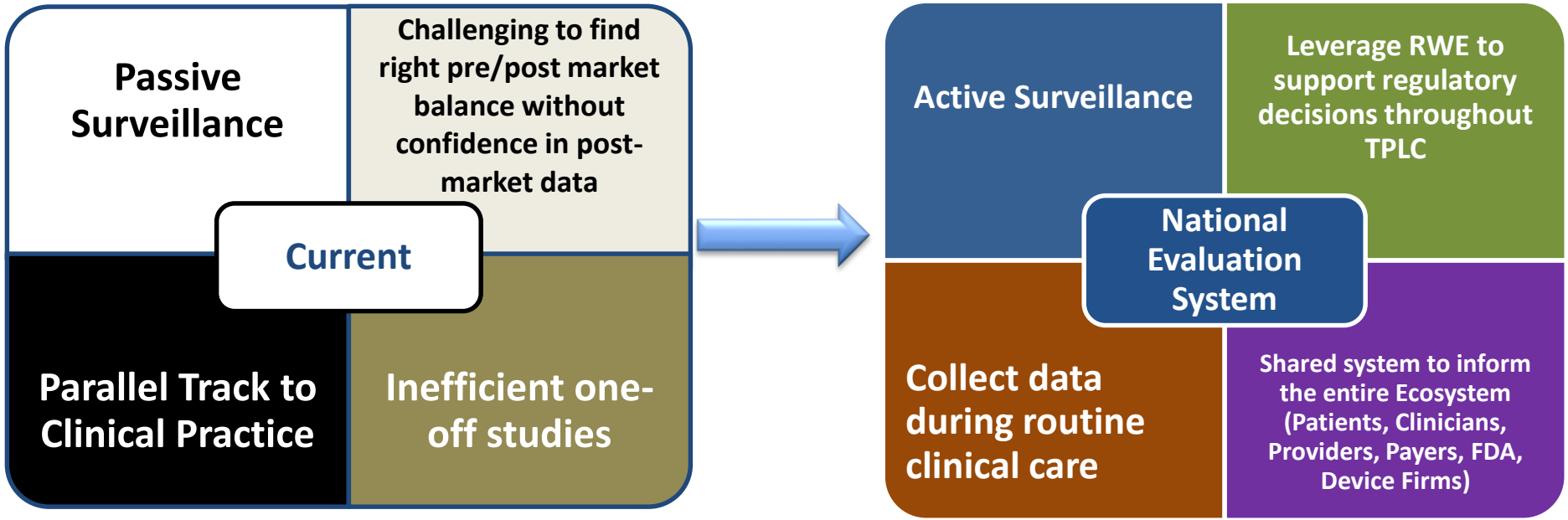
GMDN Preferred Term Name	GMDN Definition
Hepatitis B virus surface antigen IVD, kit, chemiluminescent immunoassay	A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of Hepatitis B virus surface antigen in a clinical specimen, using a chemiluminescent immunoassay method.

- **SNOMED** – recognized in US
- **UCUM** – Unified Code of Unit of Measure



- **DUNs** Number - a unique nine-digit identification **number** for each physical location of your business.

Medical Device Evaluation Paradigm Shift: Today and Tomorrow



MDIC NEST

National Evaluation System for health Technology

The MDIC is currently working to establish the NESTcc Governing Board and to initiate a series of demonstration projects capable of providing direct value to participating stakeholders

1

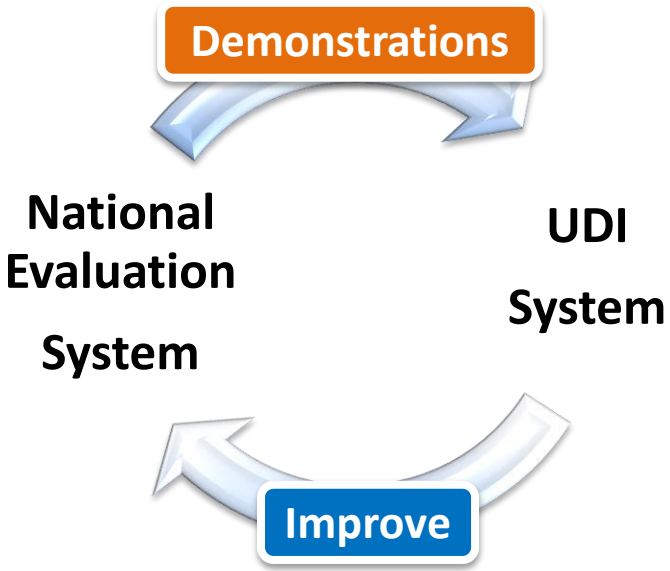
Phase 1
Establish NESTcc Governing Board with representation from patients, federal agencies, industry, clinicians, hospitals, and health plans

2

Phase 2
Initiate focused demonstration projects centered on high-risk category devices that require tracking and EHR data from hospital systems that use modern means of data collection

3

Phase 3
Demonstration projects will establish sustainability of the NESTcc to the broader medical technology ecosystem



UDI data linked to NEST will support

Patients..	be more informed healthcare consumers by having data to evaluate device performance in similar patients
Clinicians..	use more trusted source as basis of device selection . Being confident in providing care to patients with existing devices.
Government..	make decisions based upon more clear linkages between real world use of clearly identified devices
Hospitals..	take advantage of UDI in multiple sources to improve purchasing, recall management, and device safety initiatives.
Industry..	use their own UDI and master device data (in GUDID) as the standard in supply chain, EHR, registry and regulatory sources
Researchers..	access high-quality audited data and leading medical device research based on device data captured at point of care

Opportunities for Engagement

FDA working with stakeholders to identify obstacles and define best practices for ensuring UDI is the device identifier standard for master data

- April
  - Association for the Advancement of Medical Instrumentation (AAMI)
  - GS1 Global Conference
  - GHX Summit
  - MDIC Landscape Analysis Meeting
- May
  - Healthcare Manufacturers Management Council (HMMC)
- June
  - UDI Conference
  - GS1 US Conference
- July
  - Association for Healthcare Resource and Materials Management (AHRMM17)

Contact Information

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SHARING EXPERTISE

GS1 HEALTHCARE CONFERENCE

MEDICAL DEVICE IDENTIFICATION

Georg Keller Manager Regulatory Affairs/Coordinator Labeling

Berlin, 5 April 2017

UDI in USA and EU

UDI REQUIREMENTS OVERVIEW / COMPLIANCE DATES

UDI Requirements Overview

1
- Standardized Numbering for unambiguous Device Identification (UDI)

ISO-based Numbering
➢Master Data

2
- UDI on the Label or on the Medical Device itself
- human readable and machine readable Format

Barcode Identification
➢Barcode

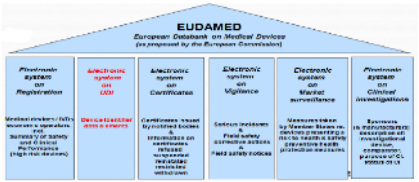
machine-readable (AIDC)
+ human-readable (HRI)

standardized Date format
‚YYYY-MM-DD'

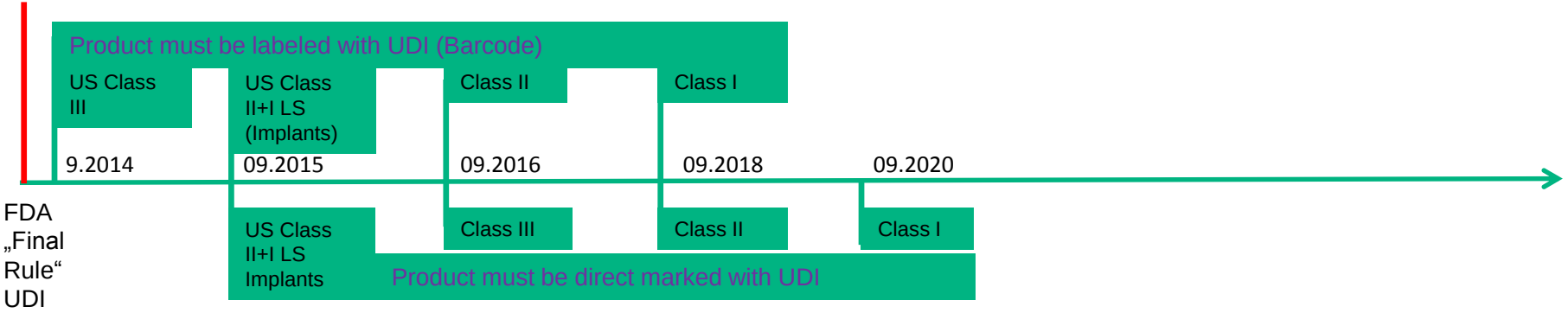
3
- Central UDI-Database with further information to the Medical Devices

Data Maintenance & Exchange
➢Processes

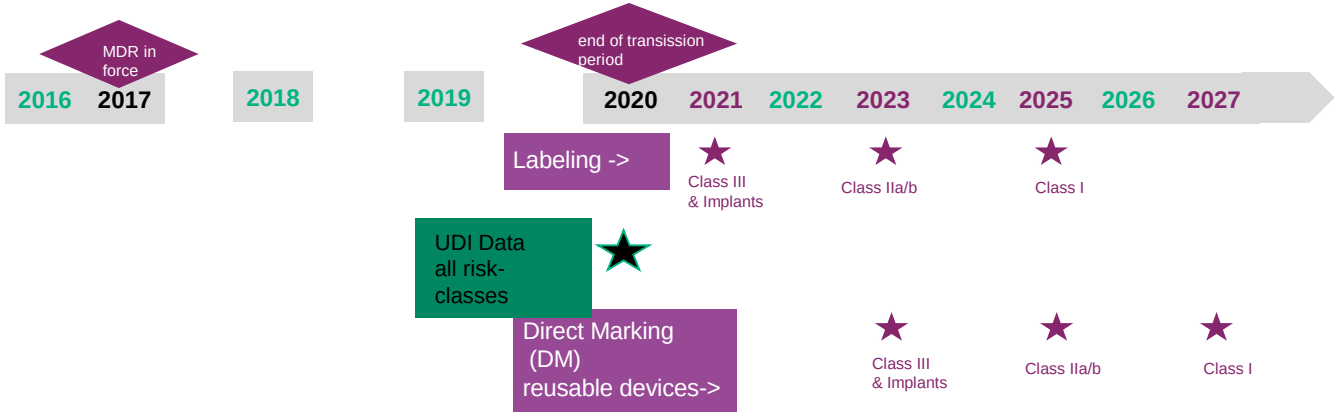
ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE



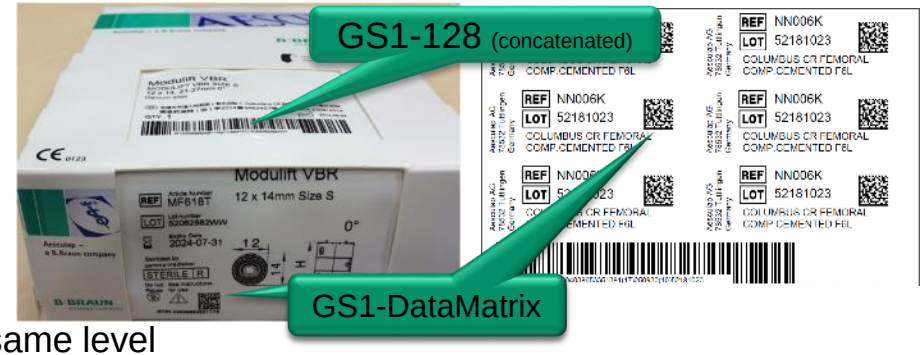
UDI Compliance Dates



MDR Timelines / Milestones



AIDC : Label Samples (DI + PI included)



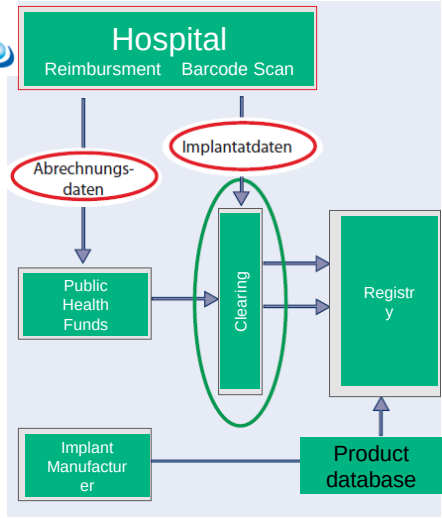
- avoid multiple barcode on the same level
- barcode on patient stickers

to serve

- Implant Registries
- Implant Card („new“ MDR requirement for Class III implants)
- Documentation (Health Records)
- Inventory Control
- Re-ordering Process

➢ UDI is used for scanning
➢ data exchange with own standards

EPRD Endoprothesenregister Deutschland



Reusable Devices …

… requiring sterilization or high-level disinfection between uses
e.g. surgical instruments

- UDI must be on the device
- UDI must be readable after each sterilization or high-level disinfection
- UDI Production Identifier be defined by the manufacturer according the QM system - e.g. lot or serial no

Exceptions possible

- DM interferes with the safety or effectiveness of the device
- DM technically not feasible

Direct Part Marking (DM) or other permanent marking method !

FDA : When a device must bear a UDI as a direct marking, the UDI may be provided through either, Plain Text‘ or, AIDC‘ or both.

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(01) 04038653020720 (21/10) 12345678

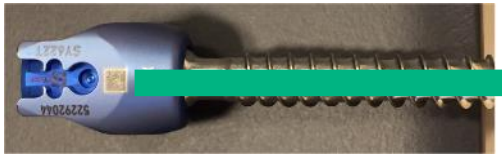
Application Identifier GTIN | Start digit | company number | article reference | Check digit | AI Serial/Lot number | Serial/Lot number (max. 20 digits)

2.5 mm

2.5 mm

x-module 0.14 mm

symbol size 18 (row/column)



2 mm

2 mm

x-module 0.11 mm

symbol size 18 (row/column)

- high-quality DPM technology required
  - (laser, dot peen, etc.)

1 mm

1 mm

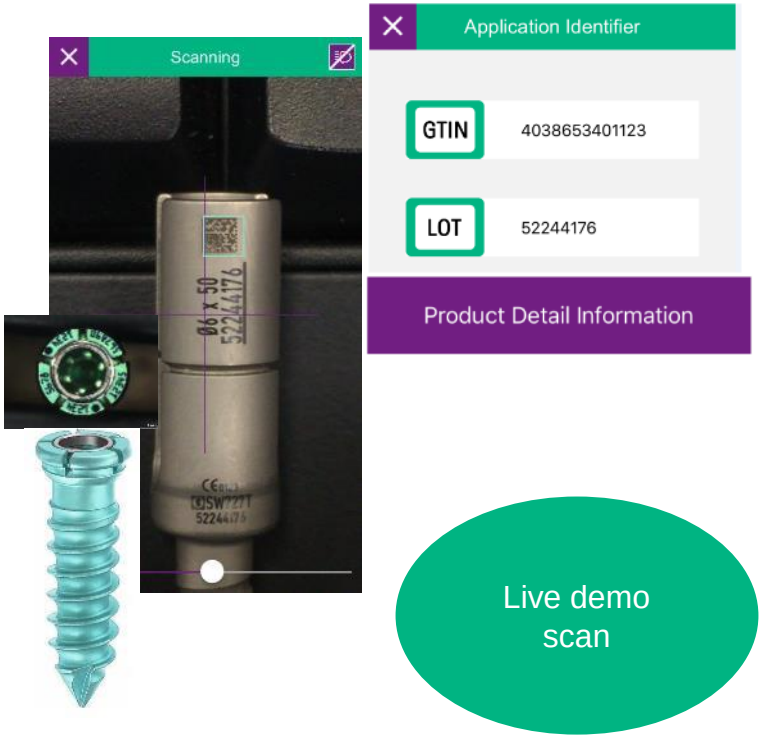
x-module 0.05 mm ???

FDA : Does not specify a method to direct mark a device.

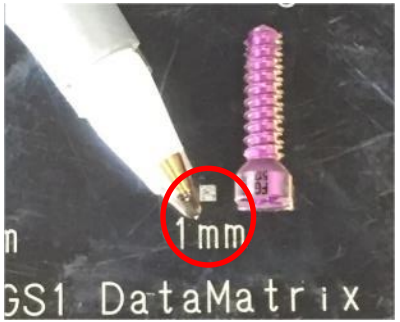
- GS1 General Specification allows 0.1mm x module size
- Reading technology is available, not covered by GS1 gen. specs

Aesculap AG

DM : AIDC vs. Human Readable Information (HRI)



Live demo scan



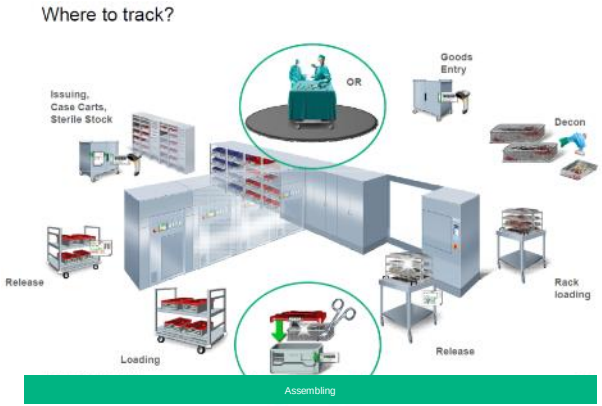
- Size of data matrix can be at a minimum 2mm (GS1 Gen. Specs) with the current data content.
- Current reading technologies would allow to read also 1mm
- AIDC should be preffered.
- Human Readable Information by itself is compliant with regulation, but is it useable?
- Does Barcode verification apply to such small codes as well?

Use of Direct Marking (DM)

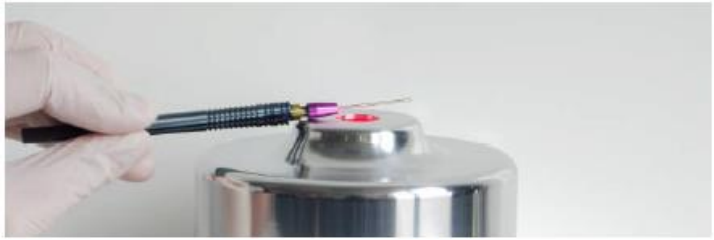
Scanning Data-Matrix with common technologies
- e.g. smartphone or tablet

Access product data, instructions
- cleaning, reprocessing
- assembling

Tracking



requires:
- ➢ good reading technologies
- ➢ documentation system



- ❑ Completeness check at the assembling place
- ❑ Maintenance intervals
- ❑ Assembling

Let‘s drive the UDI „-Van“
and use it for
- patient safety
- Reg. compliance
- improve hospital processes

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THANK YOU

FOR YOUR TIME

Panel Discussion and Q&A

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