The Global Language of Business

UDI – AIDC Implementation Experiences

32nd GS1 Global Healthcare Conference

October 18, 2017

Our Participants

Session Moderator:

- Ms. Jackie Elkin - Global Process Owner Standard Product Identification, Global Regulatory Affairs - Medtronic, United States

Speakers:

- Mr. John Terwilliger - GS1 Senior Consultant, Global Standards & Serialization Office - Abbott, United States
- Mr. Georg Keller - Manager Regulatory Affairs/Coordinator Labeling - B.Braun / Aesculap AG, Germany
- Mr. Mark Hoyle - Technical Director, UDI, Commercial Regulatory Affairs - Teleflex, Ireland

Our Programme

- **Welcome, Introductions and "*IMDRF Harmonized Unique Device Identification (UDI) Application Guide*"**
  Jackie Elkin (Moderator)
- **"*UDI – AIDC Implementation experiences at Abbott*"**
  John Terwilliger (Speaker)
- **"*UDI-AIDC Implementation Experiences – Direct Marking at B.Braun*"**
  Georg Keller (Speaker)
- **"UDI Implementation Journey at Teleflex"**
  Mark Hoyle (Speaker)
- **Open Audience Q&A**
  Jackie Elkin (Moderator)

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IMDRF Harmonized Unique Device Identification (UDI) Application Guide

New Work Item Proposal (NWIP)

Jackie Rae Elkin, Medtronic

October 18, 2017

NWIP Background

- New Work Item Proposal (NWIP) presented at March 2017 IMDRF Management Committee meeting
- Management Committee instructed GMTA to prepare first draft of the IMDRF UDI Application Guide
- Draft submitted July 7, 2017
- September 2017 - Management Committee approved NWIP (with revisions), “Harmonized Unique Device Identifier (UDI) Application Guide” (EU to chair).

Thank you!

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UDI – AIDC Implementation experiences at Abbott

Plan for UDI – AIDC Success

John Terwilliger, GS1 Senior Consultant, Abbott Laboratories

2017-10-18

UDI – AIDC Implementation: Pre-work

- Get GS1 Organized
  - Build staff, get educated, become “experts”
    - Design, implement and roll out GS1 training internally (staff buy-in)
    - Understand GS1 Company Prefix assignments
    - Adopt corporate SOPs regarding the use and governance of GS1 Standards
  - Implement Global Trade Item Numbers (GTINs) correctly
    - Implement a procedure/process for assignment
    - Correct/understand “sins of the past”
    - Incorporate the “no reuse” rule

UDI – AIDC Implementation: Pre-work, cont'd

- Establish a common understanding via education
  - Multiple business units
  - Multiple functional organizations (business and IT)
  - Multiple levels of understanding
- Create and maintain FAQs
  - Document decisions/rationale
  - Enable self-help/learning

UDI – AIDC Implementation: Pre-work, cont'd

- Get Program Organized
  - Senior Level Executive Support
  - Establish UDI Project Management Office (PMO)
  - Formal internal communication plan
  - SharePoint collaboration tool
  - Business sub-team identification
  - Detailed project planning

UDI – AIDC Implementation

- Objective:
  - Meet the UDI - AIDC requirements
  - Implement UDI - AIDC into the existing process (it is new way of life)
  - Plan for multiple countries/geographies
- Other work
  - Existing policies/procedures need to updated/changed
  - New policies/procedures need to be written

UDI – AIDC Implementation

- Ensure proper GS1 data construction
  - Correct barcode symbol types
  - Correct GTINs
  - Correct Application Identifiers
  - Function 1s present
- Ensure correctness for new business units, vendors and third-party manufacturers insist on pre-production samples of barcodes
- Ensure barcode quality
- Clean-up the label by removing extraneous barcodes – a single barcode is preferred by the clinician (no confusion)
- A warehouse “assessment” to double check barcodes

Contact Information

John Terwilliger

GS1 Senior Consultant

Abbott Laboratories

Abbott Park, IL USA

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GS1 HEALTHCARE CONFERENCE

UDI-AIDC IMPLEMENTATION EXPERIENCES

Georg Keller Manager Regulatory Affairs/Coordinator Labeling

Chicago, 18th October 2017

UDI in USA and EU

UDI REQUIREMENTS OVERVIEW

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

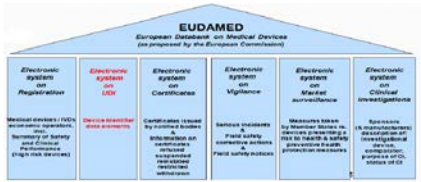
machine-readable (AIDC)
+ human-readable (HRI)

standardized Date format
‚YYYY-MM-DD'

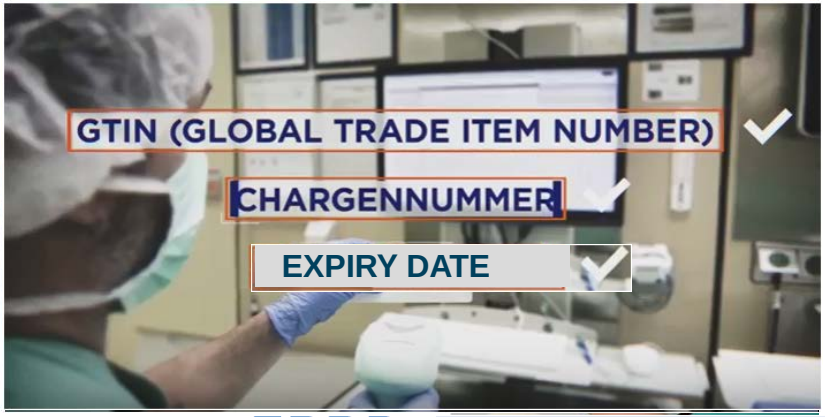
3
- Central UDI-Database with further information to the Medical Devices

Data Maintenance & Exchange
➢Processes

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE



AIDC : Label Samples (DI + PI included)



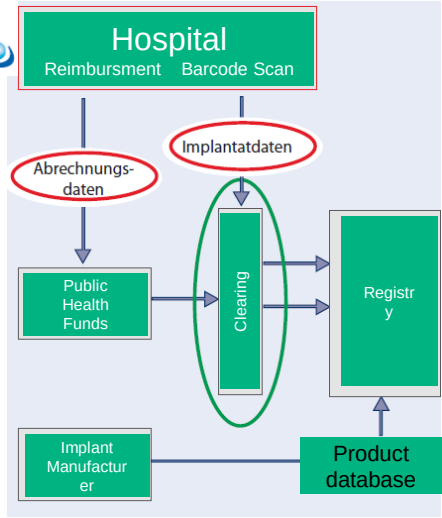
- avoid multiple barcode on the same level
- barcode on product or patient stickers

to serve

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

➢ 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

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.
EU-MDR : ‚Plain Text' **and** ‚AIDC'.

Exceptions possible

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

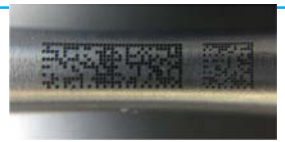
Direct Part Marking (DM) or
other permanent marking method !

Laser Marking Technologies

ns-Marking Stainless Steel:

Annealing Marking

- corrosion
- fading, chipping
- rough surface



ps– Marking Stainless Steel, etc

- Resistant against corrosion
- Independent from viewing angle
- Different Materials and surface possible to mark

- high-quality DPM technology required
  - (laser, etc)

DM : AIDC vs. Human Readable Information (HRI)

- 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?
- Barcode verification with smaller codes possible

Use of Direct Marking (DM)

Article number: DP512R

Product name: HARDWIRE CUTTER L:125MM

Instructions for use (download)

validated method | other possible methods

This shows the short description of reprocessing methods validated by Aesculap. Details about the validated reprocessing options can be found in the instruction manual. Please take not that a successful reprocessing depends on the set loading

Method applied	Description
Cleaning	mechanical alkaline cleaning
Disinfection	thermo disinfection 5 min with 9
Drying	drying at max. 120° C / 248° F
Sterilization	Fractionated vacuum process, holding time of 5 minutes at 134°C
Other important notes	

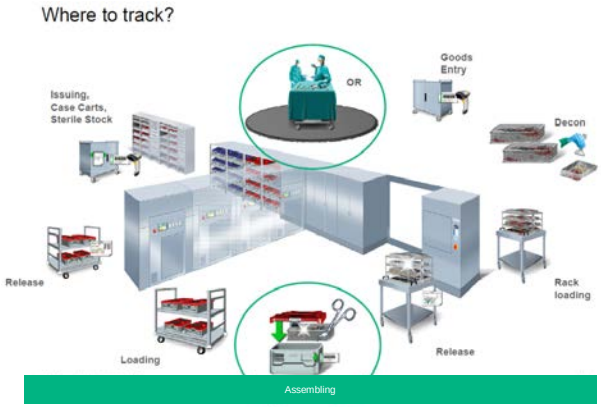
Scanning Data-Matrix with common technologies

- 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

B|BRAUN
SHARING EXPERTISE

THANK YOU

FOR YOUR TIME

UDI Implementation Journey

Mark Hoyle, Technical Director, UDI

October 2017

Teleflex®

GS1 US

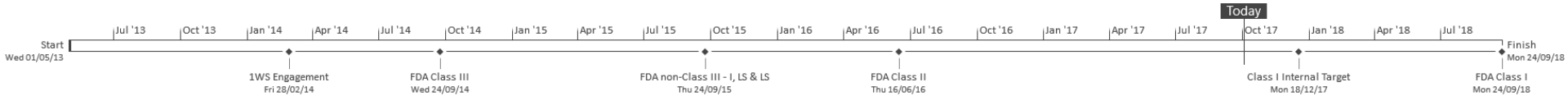
The Global Language of Business

Case Study

Teleflex

Teleflex®

Timeline & Achievements



- 1WorldSync Engagement Q2 2014
  - Validated UDI PIM (Lansa) Delivery – June 2015
  - **10K GTINs** Registered and Published Oct 2015 – non-Class III - I, LS & LS
    - Total - **25K GTINs** Registered and Published Sept 2016 – Class II
      - Target - **32K GTINs** Registered and Published **Dec 2017** – Class I (Official Target 24th Sept 2018 now extended by FDA to 2020)

US Target Market Only

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Understanding Requirements

UDI is Complex, Building a Solution is Equally Complex

Company Milestones

2015:

- Acquired Human Medics, a distributor of Teleflex products in Korea
- Acquired Truphatek, a manufacturer of disposable and reusable laryngoscope devices
- Acquired Trintris Medical, an OEM supplier of balloon catheters
- Acquired exclusive North American distribution rights to AutoFuser® range of disposable pain pump products from Ace Medical
- Acquired N. Stenning & Company, a distributor of Teleflex surgical products in Australia
- Acquired Atsina Surgical, a developer of surgical clips
- Acquired Nostix LLC, Catheter Tip Placement Solutions

2014:

- Acquired assets of MiniLap Technologies, Inc.
- Acquired Mayo Healthcare, a distributor of Teleflex products in Australia< /li>

2013:

- Acquired Eon Surgical, Ltd, micro-laparoscopy surgical technology
- Acquired Ultimate Medical and its affiliates, technology for laryngeal masks and other airway management devices
- Acquired Vidacare Corporation, leading technology platform for intraosseous access devices

2012:

- Acquired assets of Axiom Technology Partners,
- Acquired EZ-Blocker™ disposable catheter
- Acquired Hotspur Technologies, Inc.
- Divested OEM Orthopedics business
- Acquired assets of LMA International N.V. ("LMA")
- Acquired Semprus BioSciences

2011:

- Divested Marine Business
- Acquired VasoNova Inc.
- Divested Aerospace Business

Challenge

We faced various options about how to approach and implement a data management solution to comply with the U.S. Food and Drug Administration’s (FDA) Unique Device Identification (UDI) regulation.

We also wanted to ensure a solution that would help address other worldwide regulatory requirements in the future as well as the needs of our customers for sharing trusted product data.

Master Data Complexity

ERP 1

ERP 2

ERP 3

PLM 1

PLM 2

Design Files

Spread-sheets

PIM 1

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

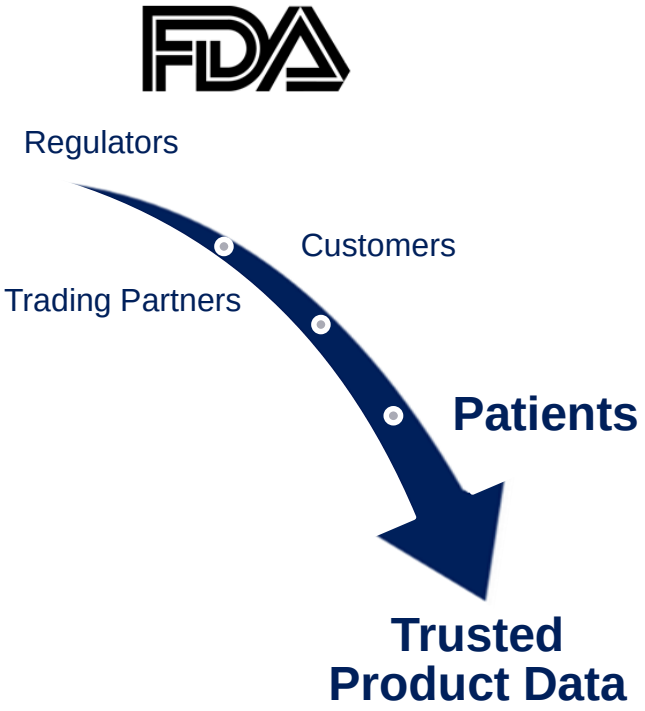
Teleflex®

Data Standards Drive Quality, Enabling Interoperability

The Solution

LANSA Data Sync Direct & 1WorldSync

Business Partnerships



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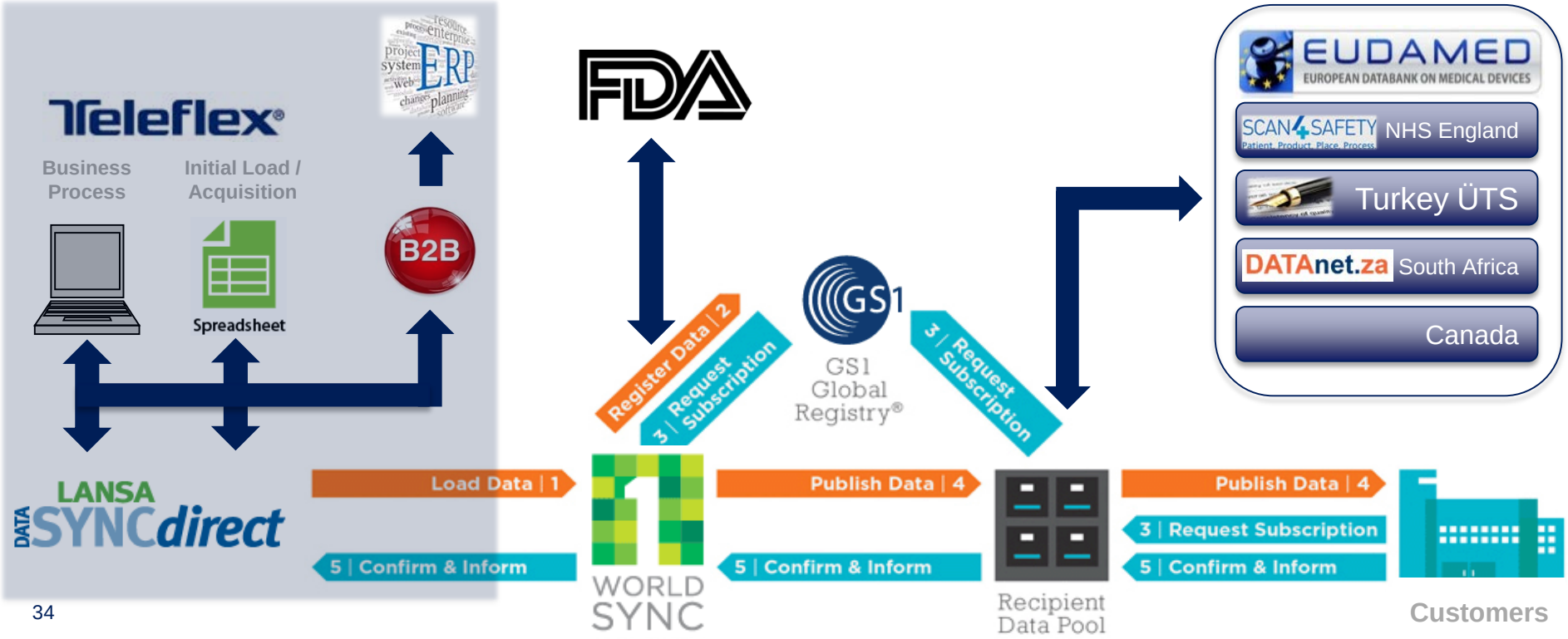
The Solution

We developed processes to assign and **validate** each **GTIN®** and associated attributes on their way to the FDA's Global UDI Database (GUDID). We also achieved **GDSN®** operability for trusted data-sharing with trading partners and customers.

UDI System & GDSN

Target Market Extension



Automation & Data Volume

- Interoperability is vital especially with large data volume
  - 17,000 SKUs ~ 5.5M Attributes (Single Target Market – USA)

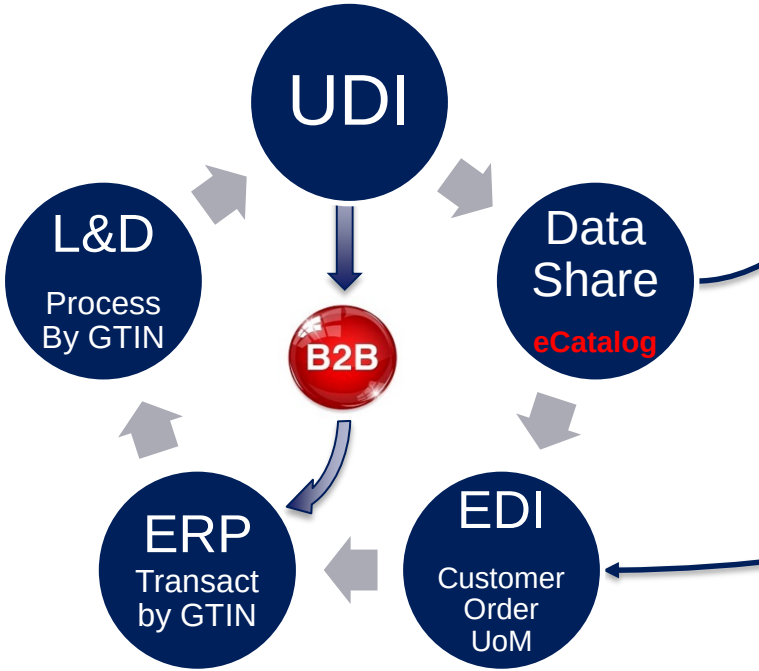
The Benefits

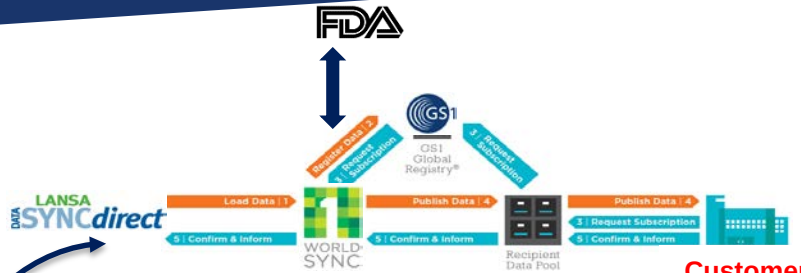
By implementing a GS1 Standards-based approach, we can provide “a single version of truth” associated with accurate, complete, and validated product data to all Healthcare stakeholders.

We have utilised GS1 Standards for improvements in our operations that meet regulatory obligations, enabling greater patient safety, and care provider requirements.

How does it work?

The 360º Cycle of GTIN Usage





Customer eCatalog

Order UoM & GTIN

Order Using GTIN & GLN

Teleflex®

Project or Process?

- UDI is not a Project, it’s a **Validated Process**!
- Needs constant monitoring and engagement
- Embedded into our QMS
- Driven by creation, change and termination of products

Communications - Organisational Change Management

- Customer Facing Website:
  - http://www.teleflex.com/usa/services/unique-device-identification/

- Case Study – Teleflex®, WORLD SYNC, LANSA DATA SYNCdirect

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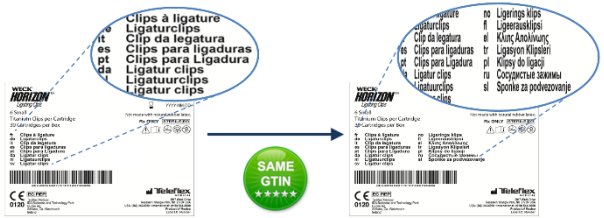
The Challenges

Change Management and Equivalency (1)

- Device Identifiers (GTIN's) are subject to change
  - Regulation
    - Governance rules from FDA
    - EU MDR – Change Requirement
  - GTIN Allocation Rules – GS1 Healthcare



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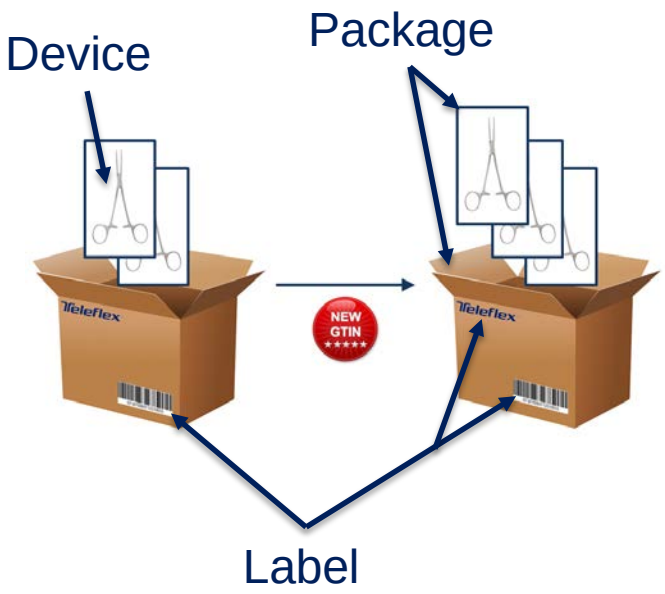
Change Management and Equivalency (2)



- The **Product** = **Device + Package + Label**
- The same **Device** can be contained in many **Products** globally and is therefore **‘Functionally Equivalent’**

e.g. A label change, regulatory in nature can limit market distribution ability. GTIN – Global Trade Item Number is used to manage supply chain.

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UDI Responsibilities – Who's GTIN?

- Labeller Definition is challenging, responsibilities blurred?
- EU MDR – Possibly a little clearer! [1.]
- Does interpretation pose any risk?
  - UDI intent, is it logical if responsibility is not consistent – PRRO / Brand Owner?
  - Is OBL (Virtual Manufacturing) at risk?
  - Or, is visibility of the OEM hidden from within the UDI?
  - Is brand protection challenged in International markets?
  - Is there an impact of misalignment of regulatory lifecycle data?

[1.] MDR Part C Annex VI 2.2 & 2.3 & Article 2 (30)

UDI regulatory compliance helps Teleflex deliver even greater levels of patient safety.

"Making considered decisions upfront by understanding the present and future vision is critical; you will reap many benefits downstream. These benefits will be realized through accuracy and efficiency along the supply chain, ultimately leading to improved patient care."

Mark Hoyle
Technical Director, UDI
Teleflex

Teleflex®

And now… Audience Q&A…

Networking Dinner on Wednesday, 7:00 pm

John G. Shedd Aquarium

1200 S Lake Shore Dr.
Chicago, IL 60605

Meet in the main lobby for shuttle bus departure: 6:30 pm

Return shuttle buses: beginning 8:00 pm until 10:15 pm, running on a loop between locations

Dress code: business casual.

Please wear your event badge ☺