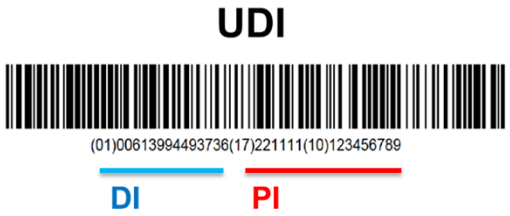


# UDI Implementation for IVDs

**2014 AMDM Annual Meeting**
**April 10, 2014**

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**Division of Microbiology Devices**
**Office of In Vitro Diagnostics and Radiological Health**
**FDA, Center for Devices & Radiological Health**

# BLUF (Bottom Line Up Front)

## What do you need to know…

- Final rule, published 9/24/2013
- GUDID, draft guidance published 9/24/2013
- Where to get help (UDI help desk)

## FDA resources are at:

- http://www.fda.gov/udi

## If you are uncertain…

- Ask via the UDI help desk (link at web address above)

# Overview

- **General**
  - What is it
  - What does it look like (format, contents, etc.)
- **Specifics**
  - IVDs and UDI
  - Compliance dates
- **GUDID**
  - What is it
- **Getting Help**
- **Questions (maybe)**

# UDI Legislation Authorization
## FDAAA 2007, FDASIA 2012

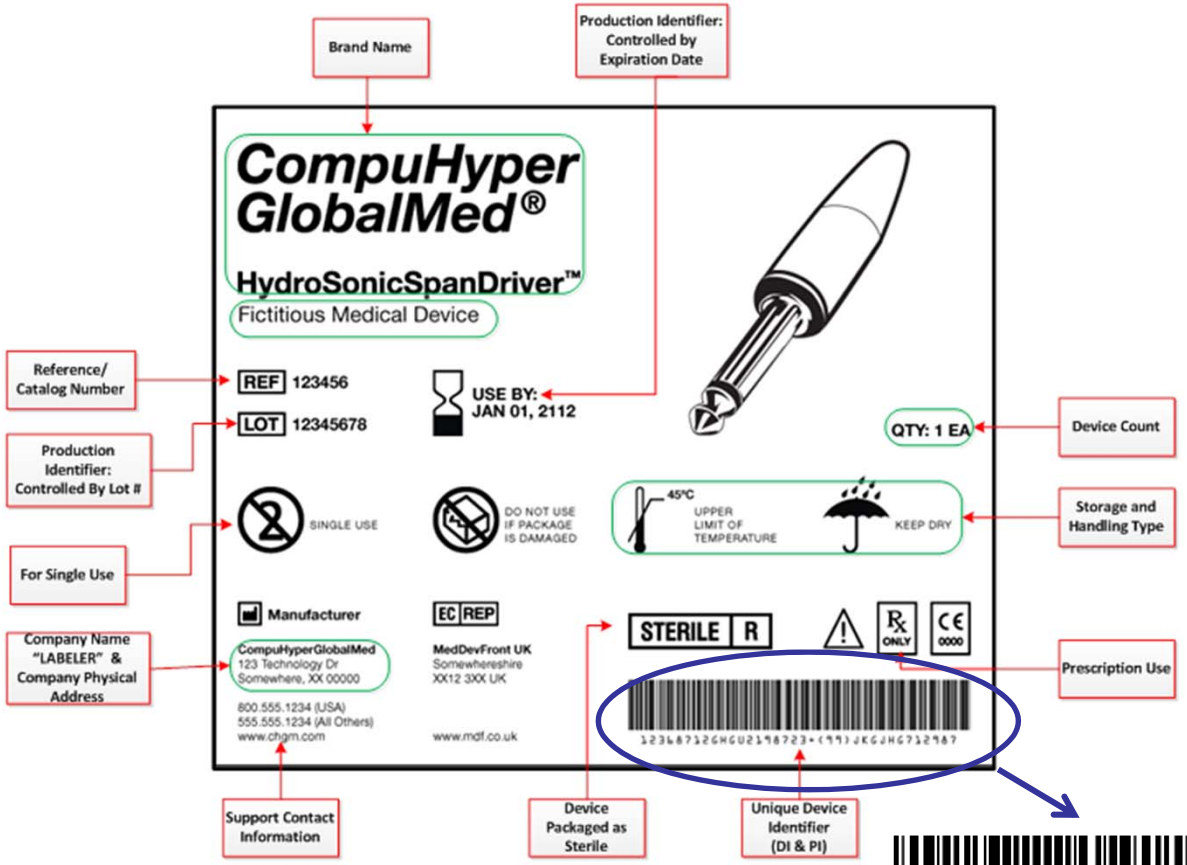
Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the **label of devices to bear a unique identifier**, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier **shall adequately identify the device through distribution and use**, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.

http://www.gpo.gov/fdsys/pkg/PLAW-110publ85/html/PLAW-110publ85.htm
http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf

# So What is a Unique Device Identifier

- A Unique Device Identifier (UDI) is a **globally unique** number that identifies (almost) every individual medical device
- Number will be on the labels and packages of (almost) all medical devices
  - 'Base' packaging and higher levels
- Per the legislation, "may include information on the lot or serial number"
- The long-sought 'Master Data Manager'?

# An Example…


Brand Name
Production Identifier: Controlled by Expiration Date
CompuHyper GlobalMed®
HydroSonicSpanDriver™
Fictitious Medical Device
Reference/ Catalog Number
REF 123456
LOT 12345678
USE BY: JAN 01, 2112
QTY: 1 EA
Device Count
Production Identifier: Controlled By Lot #
SINGLE USE
DO NOT USE IF PACKAGE IS DAMAGED
45°C UPPER LIMIT OF TEMPERATURE
KEEP DRY
Storage and Handling Type
For Single Use
Manufacturer
EC REP
STERILE R
Company Name "LABELER" & Company Physical Address
CompuHyperGlobalMed
123 Technology Dr
Somewhere, XX 00000
800.555.1234 (USA)
555.555.1234 (All Others)
www.chgm.com
MedDevFront UK
Somewhereshire
XX12 3XX UK
www.mdf.co.uk
Prescription Use
Support Contact Information
Device Packaged as Sterile
Unique Device Identifier (DI & PI)
UDI
(01)00613994493736(17)221111(10)123456789
DI
PI

# UDI Format

- Format is plain text and machine readable format for Automatic Identification and Data Capture (AIDC)
  - Format is technology neutral, e.g., classic bar code, 2-D bar code, RFID, etc.
  - There's a good bit of flexibility…
- DI = mandatory, PI = conditional
  - I'll explain this…

# Unique Device Identifier (UDI)

- **UDI = (DI) + (PI)**


  - DI = Device Identifier
    - Globally-unique number
    - Issued by FDA-accredited Issuing Agencies, not FDA itself
      - Appearance/'structure' may differ based on issuing agency; the content is the same
  - PI = Production Identifier(s) [Class I does not need PI(s)]
    - Identifies manufacturing controls
      - Lot/Batch #
      - Serial # (specific unit)
      - Expiration date
      - Manufacturing date
      - ID code for cellular and tissue-based product (HCT/P) regulated as a device.
    - Each UDI contains ≥1 PI
    - The intention of the PI(s) is to be consistent with present device labeling so that sponsors do not need to change their process to accommodate UDI

# In Vitro Diagnostics and UDI…

- UDI is applied at the 'make/model' level
- IVD products with UDI
  - Lab equipment
  - All test kits
  - Additional reagents
  - …anything that is available for individual sale should have its own UDI
- IVD products without UDI
  - Single instance of an IVD test (most tests come in a kit of multiple test instances, the UDI is on the kit.)
  - Components of a test kit (unless that same component is also available for individual sale)

# In Vitro Diagnostics and UDI

- Single use devices:
  - UDI on each distributable package; no individual UDI for each device
  - UDI only on higher-order package if distributed together in a single device package with intent to be stored until removal for use, and not intended for individual commercial distribution


- Kits: only the kit needs a UDI
- Combination products: NDC OK on package, but device component inside needs UDI on label

- NB: A fair number of exceptions/exemptions/etc. exist throughout the final rule (details matter)
- FDA grants exceptions (or alternatives) that may extend to classes of devices (precedents matter)

# Compliance Dates

- Year 1: Class III and devices licensed under PHS act (started 9/24/2013)
- Year 2: Class II implants and life supporting-sustaining devices (defined by certain procodes)
  - Stand-alone software that is a life-supporting or life-sustaining device
- Year 3: Remainder of Class II
- Year 5: Class I (Class I with UPC can use that as UDI)

- *NB: there are separate compliance dates for also having permanent markings on devices intended to be used more than once and reprocessed before each use*
- *NB: Some exceptions, including existing inventory*

# GUDID –Database
# Global Unique Device Identification

- Stores device identifier (DI) and other regulatory device identification information (not PI product identifier information)
- Accessible for integration – Potential to link device information within FDA and in healthcare systems - procurement, inventory control, recalls, clinical care (including registries and clinical trials), clinical material management, incident systems etc.

# Global Unique Device Identification Database (GUDID)

- Labelers must register and then enter information for each UDI
- Web-based interface
- Basically capture the information on the package label (not package insert)
- Initially limited to Class III and PHS Act devices

# What is a Labeler?

A Labeler is “any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.”

# GUDID Elements

- DI (device identifier) number (and issuing agency)
- Number of individual devices in each base package
- Type of PI(s) on label, not actual PI content
- Proprietary/trade names for device
- Previous DI if new version
- Version/model number
- Size
- Premarket status (510(k), PMA, etc. ), premarket number, supplement
- GMDN term (to be discussed shortly)
- Commercial distribution status
- Higher levels of packaging
- Whether Kit, combination product, or tissue product
- Latex? Sterile? Rx or OTC?
- MRI Compatible (safe, conditional, unsafe)

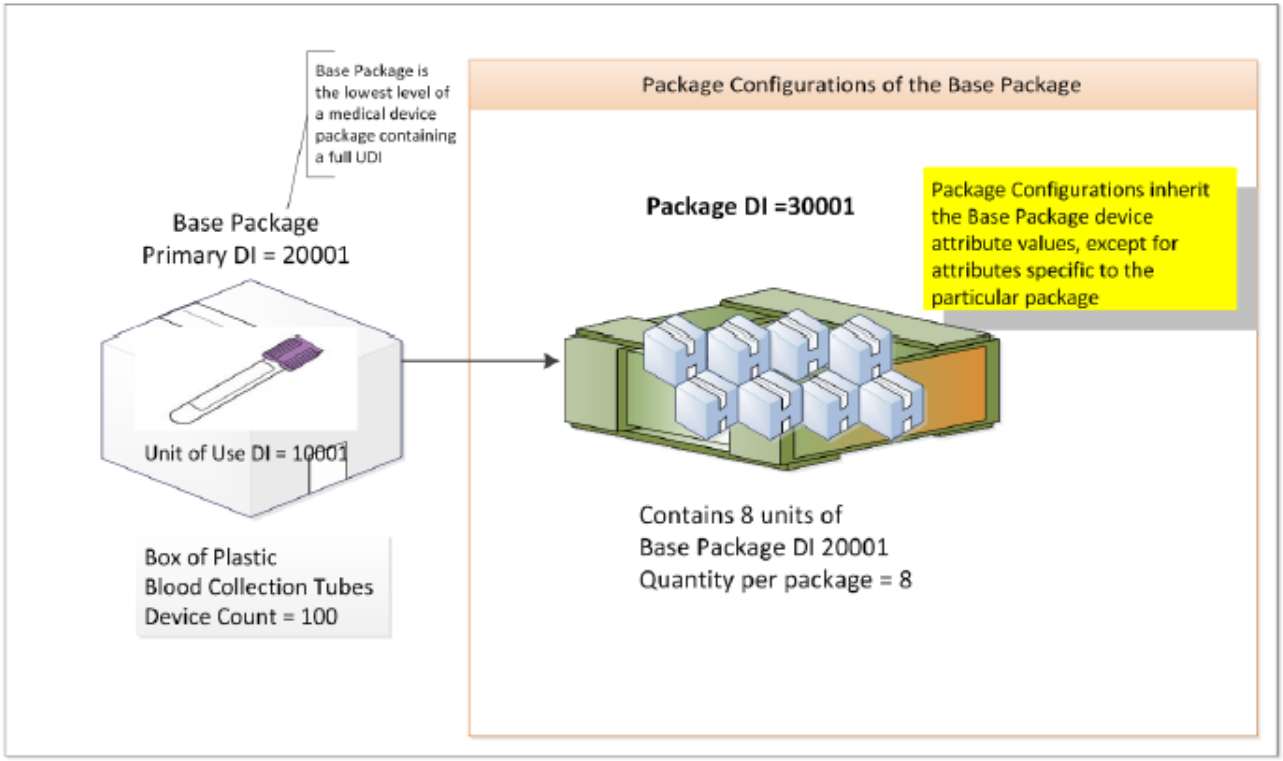
# GUDID Elements

- Company name, address, DUNS number
- Device description
- Commercial distribution end date (date the device is no longer held or offered for sale, though may still eb available)
- Support contact
- Exempt status
- Size
- Storage and Handling

*NB: Some GUDID fields will be publically available, others (e.g., company address) private*

*See Appendix B, GUDID Guidance for complete details on these (and other) fields*

# Packaging Levels

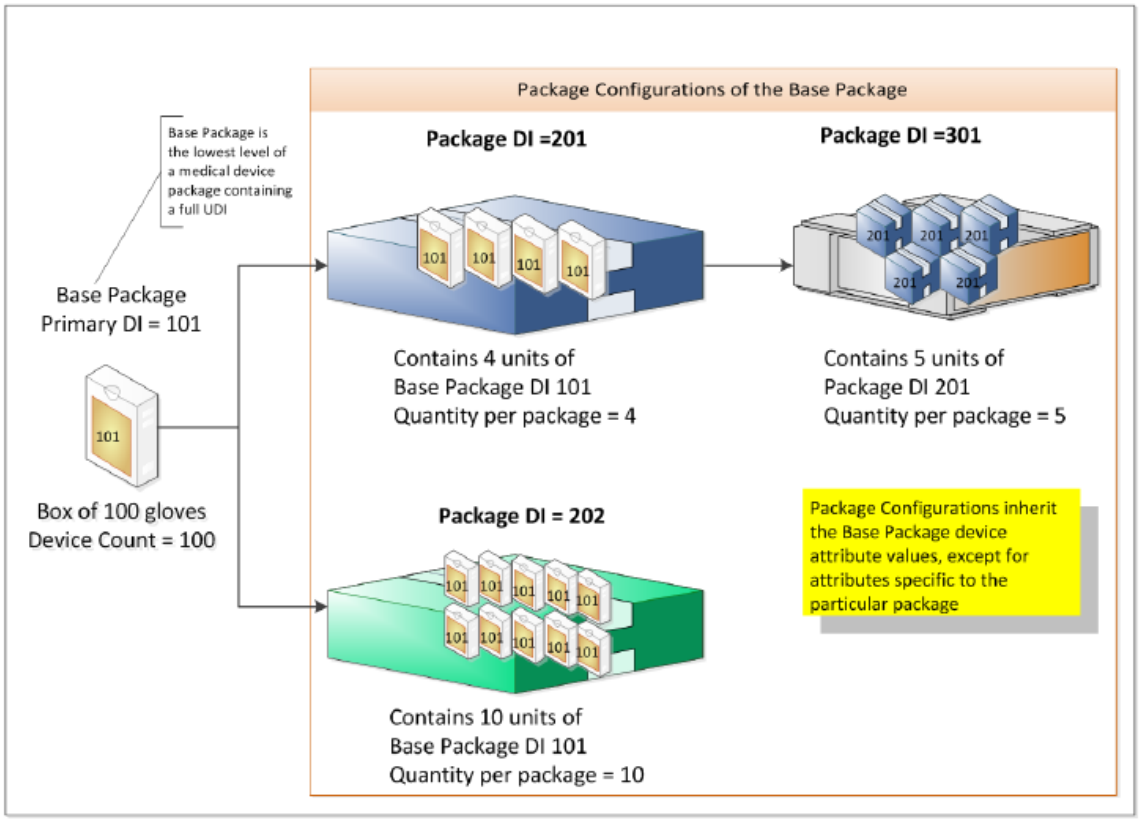



**Base Package**

| Primary Device Identifier | Device Count | Unit of Use DI |
|---|---|---|
| 20001 | 100 | 10001 |

**Package DI**

| Package DI | Quantity per Package | Contains DI Package | Package Type | Package Discontinue Date | Package Status |
|---|---|---|---|---|---|
| 30001 | 8 | 20001 | Carton | | In Commercial Distribution |




**Base Package**

| Primary Device Identifier | Device Count |
|---|---|
| 101 | 100 |

**Package DI**

| Package DI | Quantity per Package | Contains DI Package | Package Type | Package Discontinue Date | Package Status |
|---|---|---|---|---|---|
| 201 | 4 | 101 | Box | | In Commercial Distribution |
| 301 | 5 | 201 | Case | | In Commercial Distribution |
| 202 | 10 | 101 | Carton | | In commercial Distribution |

# Global Medical Device Nomenclature (GMDN)

"The foremost purpose of the GMDN is provide a single, global, nomenclature system by which the authorities can regulate medical devices; this also impacting upon the health care providers, that are the mainstay users of medical devices, the medical device manufactures, suppliers, conformity assessment bodies and other affiliated parties, so that there is only

.

The GMDN code represents the generic descriptor (this being the term name along with its definition) in order to internationally standardize device identification for reasons of safe data exchange between competent authorities and others, exchange of post-market vigilance information, research, medical record keeping, e-commerce, and inventory purposes."

# GMDN Categories

| | |
|---|---|
| 01 Active implantable devices | 10 Single use devices |
| 02 Anesthetic and respiratory | 11 Assistive products for persons with disability |
| 03 Dental devices | **12 *Diagnostic and therapeutic radiation devices*** |
| 04 Electro mechanical medical devices | 13 Complementary therapy devices |
| 05 Hospital hardware | 14 Biological-derived devices |
| **06 *In vitro diagnostic devices*** | 15 Healthcare facility products and adaptations |
| 07 Non-active implantable devices | 16 Laboratory equipment |
| 08 Ophthalmic and optical devices | 17 Medical Software |
| 09 Reusable devices | 18 – 20 Vacant |

# I Know the Next Few Slides Will be Unreadable, but…..

- The specific details aren't too important
- This way you can't ask me questions about the slides that I probably can't answer anyway

## Term Details

Product Identifier
Created 10/08/2010 17:29:11
Modified 22/12/2010 18:39:23

Term C-erbB2/Her2/neu oncoprotein IVD, antibody

GMDN Code **57047**

Definition One or multiple immunoglobulins capable of binding to specific antigenic determinants and intended to be used for the qualitative and/or quantitative detection of c-erbB2 oncoprotein, also known as Her2 or neu oncoprotein, in a clinical specimen.

**Categories**

06 In vitro diagnostic devices

**Collective Terms**

- Device Applications
  - CT954 In vitro diagnostic medical devices (IVDs)
    - CT350 Analyte assay IVDs
      - CT901 Histology/Cytology IVDs
        - CT1056 Immunohistology cell marker IV
      - CT902 Human genetics IVDs
        - CT929 Acquired genetic alteration IVDs

# Expertise May Be Needed….

- GMDN Hepatitis C Entry (48382):

**Term Details**
Product Identifier
Created 11/12/2009 19:41:55
Modified 11/12/2009 19:41:55

| | |
|---|---|
| Term | Hepatitis C virus antibody/antigen IVD, kit, chemiluminescent immunoassay |
| GMDN Code | **48382** |
| Definition | A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of Hepatitis C virus antigens and antibodies to Hepatitis C virus antigens in a clinical specimen, using a chemiluminescent immunoassay method. |
| Related bulletins | Hepatitis C virus antigen/antibody kit term is obsolete. Use more recent developed P terms or alternative active P terms such as: Hepatitis C virus antibody/antigen IVD, kit, enzyme immunoassay, Hepatitis C virus antibody/antigen IVD, kit, chemiluminescent immunoassay |

**Categories**
06 In vitro diagnostic devices
**Collective Terms**
- Device Applications
  - CT954 In vitro diagnostic medical devices (IVDs)
    - CT350 Analyte assay IVDs
      - CT701 Infectious disease IVDs
        - CT355 Viral infectious disease IVDs
          - CT352 Hepatitis virus IVDs
            - CT705 Hepatitis C virus IVDs

- Some examples may not be straightforward…

# Getting Help

# Help?

- Good News: not ‘too’ many OIR PMAs
- Send questions to: udi@fda.hhs.gov; they will respond promptly
- General information is available at: http://www.fda.gov/udi

# In Closing……

- UDI and GUDID are both invaluable advances that will fundamentally change EMRs, research, device epidemiology, labeling, and compliance….
- Implementation is (appropriately) is being done in a very measured manner (with a developmental feedback loop)….
- If uncertain, ask!