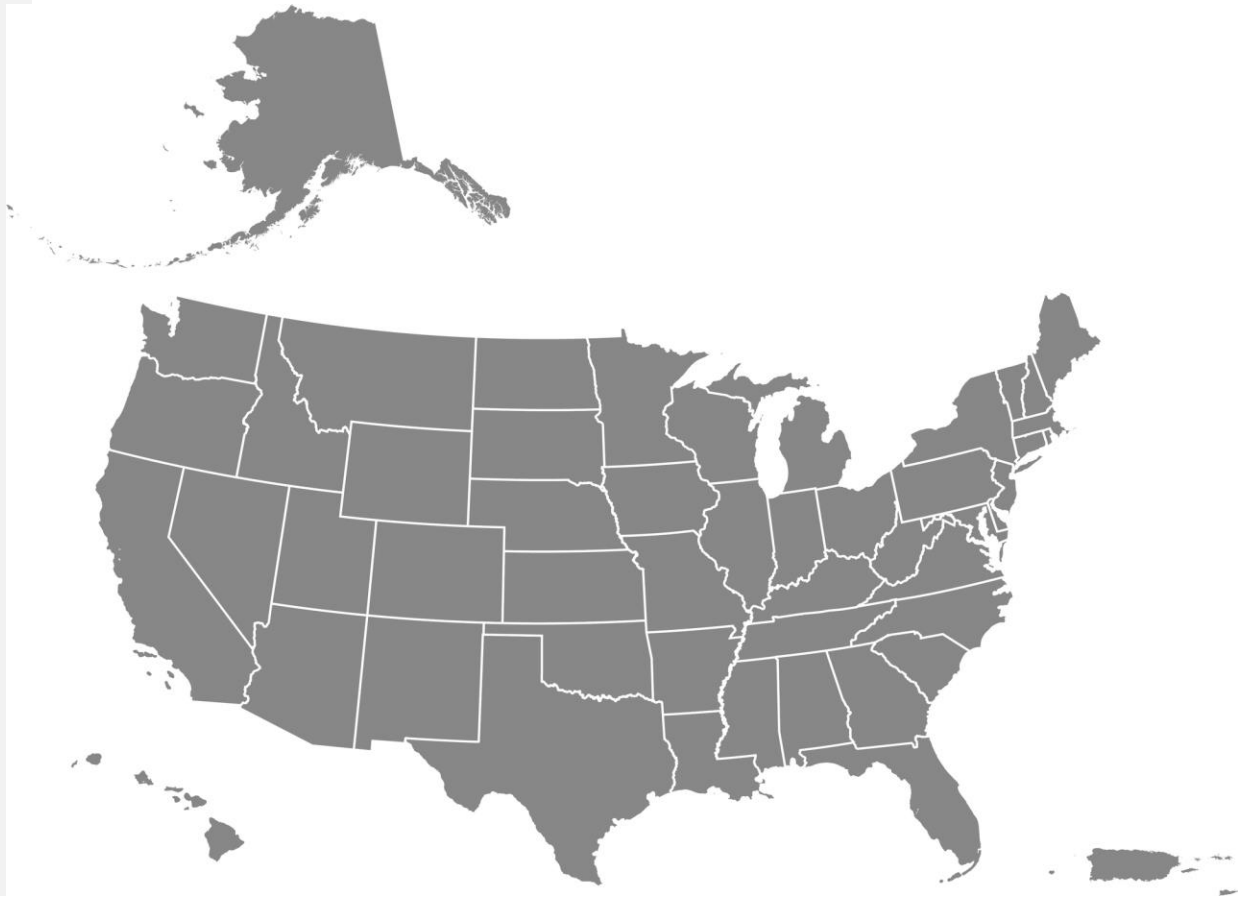
Medical Devices

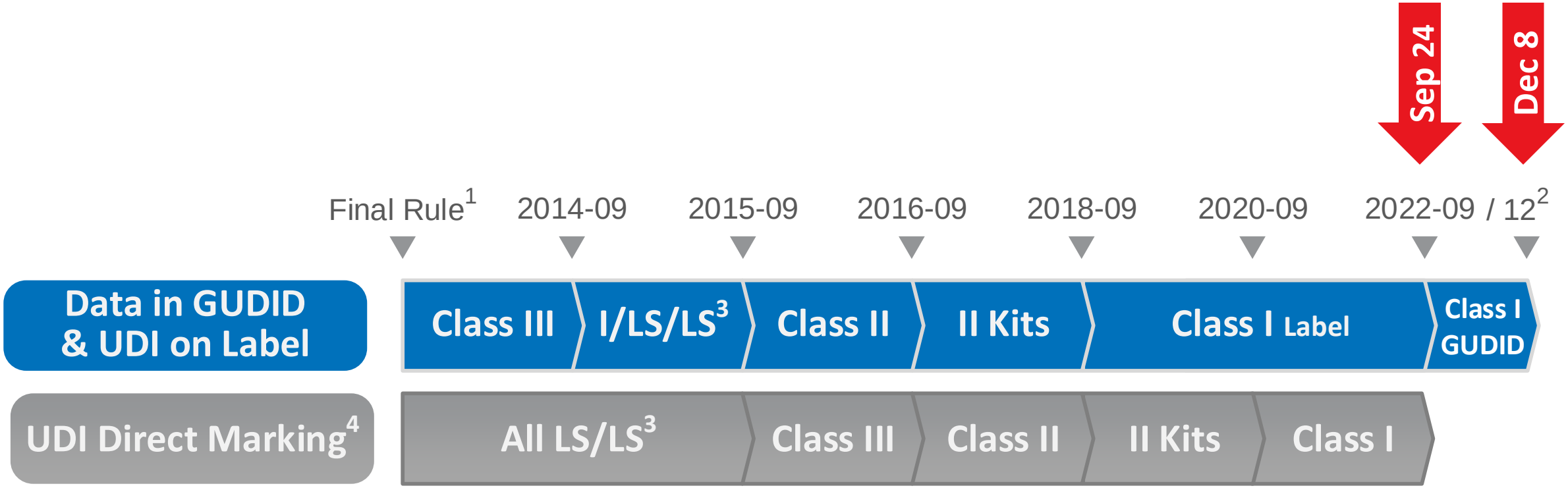
US FDA

Unique Device Identification (UDI)



Current as of: 032023

FDA UDI Compliance Timeline



1) FDA UDI Final Rule published 2013-09-24
2) Class I UDI Label and Direct Mark = 2022-09-24, GUDID Submission = 2022-12-08
3) I/LS/LS = Implantable, Life-supporting, and Life-sustaining devices
4) Direct Marking (DM) required if multiple patients and undergo high-level disinfection and/or sterilization between use

FDA Final Rule

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U.S. – FDA

Events

2013-Sep-24	Final Rule published
2022-Jul-25	GFI Class I Label due 2022-Sep-24, Class I GUDID due 2022-Dec-08, Class I OTC GUDID Exception

Compliance Timing

2014-Sep-24	Class III Devices
2015-Sep-24	I/LS/LS Devices
2016-Sep-24	Class II Devices
2022-Sep-24	Class I Devices (label, direct mark)
2022-Dec-08	Class I Devices (GUDID)

Description

- ***Approach*: UDI data reported & on labels by class; no change to device approval/registration**
- ***Database*: GUDID; functional; 3.8M records in public AccessGUDID**
- ***Data*: 57 reported attributes**
- ***Sub*: website entry or M2M SPL file via ESG**
- **Label: HRI & AIDC; Direct Mark**
- **STD: GS1/HIBCC/ICCBBA; DUNS; GMDN/FDA**
- **Info: FDA UDI**

I/LS/LS = Implantable, Life-Supporting, Life-Sustaining Devices; GFI = Guidance For Industry

FDA – Food and Drug Administration

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US FDA GUDID: UDI Data (64 total)

Identification

Pri DI Issuing Agency
Primary Device Id #
Brand Name
Version/Model #
Catalog #
Device Description
Sec DI Issuing Agency
Secondary DI #
Prev DI Issuing Agency
Previous DI #
DM Exempt (Y/N)
DM DI Different (Y/N)
DM DI #

Labeler

Labeler DUNS #
Labeler Name+
Labeler Address+
Contact Phone
Contact Email

Regulatory

Publish Date
Distribution End Date
Distribution Status+
GMDN Code
GMDN Name+
GMDN Definition+
FDA Product Code
FDA Product Code Name+
Premrkt Exempt (Y/N)
Premrkt Submission #
Supplement #
FDA Listing #
Rx (Y/N)
OTC (Y/N)

57 Submitted by Labeler
7 Populated by FDA (+)

Safety Info

Single Use (Y/N)
Contains Rubber (Y/N)
Not Made with Rubber (Y/N)
MRI Safety Status
Sterile Pkg (Y/N)
Sterile Req'd (Y/N)
Sterile Method

Packaging

Device Count
Unit of Use DI #
Pkg DI #
Pkg Quantity
Pkg Contains DI #
Pkg Type
Pkg Discontinue Date
Pkg Status+

Characteristics

Kit (Y/N)
Combo Product (Y/N)
HCT/P (Y/N)
Size Type
Size Value
Size Unit
Size Text
Storage & Handling Type
S&H Low value
S&H High Value
S&H Unit
Storage Conditions

Production Control

Lot/Batch # (Y/N)
Serial # (Y/N)
Mfg Date (Y/N)
Expiration Date (Y/N)
Donation Id # (Y/N)

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