

## **Unique Device Identifier Timelines**

## **Compliance Date**

September 24, 2014\*
Labels and packages of:
Class III devices [§801.20],
plus...

September 24, 2015
Labels and packages of:

Implantable, life-supporting & life-sustaining devices [§801.20], plus...

September 24, 2016
Labels and packages of:

Class II devices & Software [§801.20], plus...

September 24, 2018 Labels and packages of:

Class I devices & Software [§801.20], plus...

**September 24, 2020** 

The final hurrah...

## Requirements

- Class III stand alone software [§801.50(b)]
- Devices licensed under the Public Health Service Act [§801.20]
- Dates on labels must be formatted as YYYY-MM-DD [§801.18]\*\*
- Data for these devices must be submitted to GUDID [§830.300]
- Life-supporting/life-sustaining Stand-Alone Software must have UDI [§801.50(b)]
- Life-supporting/life-sustaining devices must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]
- Dates on labels must be formatted as YYYY-MM-DD [§801.18]\*\*
- Data for these devices must be submitted to GUDID [§8300.300]
- Class III devices must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]
- Dates on labels must be formatted as YYYY-MM-DD [§801.18]\*\*
- Data for these devices must be submitted to GUDID [§830.300]
- Class II devices must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]
- Devices that have not been classified as Class I, Class II or Class III [§801.20]
- Dates on labels of ALL devices, including devices exempted from UDI labeling requirements must be in YYYY-MM-DD format [§801.18]\*\*
- · Data for these devices must be submitted to GUDID
- Class I devices and devices that have not been classified as Class I, Class II or Class III must have UDI as permanent mark if it is to be used more than once and reprocessed before each use [§801.45]

