# FDA UDI Timeline

The FDA used a phased approach for their final rule.[5]
Key dates and requirements are outlined in the table below.

| Deadlines (24 Sept) | Rule |
|---|---|
| Phase 1: 2014 | Labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must:<br>• Have a UDI (including software)<br>• Dates formatted as required<br>• Data submitted to the GUDID<br>• Request a 1-year extension if not able to meet the above requirements |
| Phase 2: 2015 | Labels and packages of implantable, life-supporting and life-sustaining devices must:<br>• Have a UDI (including software)<br>• If a reusable device and reprocessed before each use, must have the UDI permanently imprinted on the device<br>• Data submitted to the GUDID |
| Phase 3: 2016 | Class II devices, intended to be used more than once and reprocessed before use must:<br>• Have a UDI (including software)<br>• Dates formatted as required<br>• Data submitted to the GUDID Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database |
| Phase 4: 2020 | Class I intended to be used more than once and reprocessed before use , class I, and devices not classified into class I, II, or II, or those that had previously been exempt, intended to be used more than once and reprocessed before use must:<br>• Have a UDI (including software)<br>• If a reusable device and reprocessed before each use, must have the UDI permanently imprinted on the device<br>• Dates formatted as required |

This chart is used for high-level communication purposed only.

Please see the Federal Register, Vol. 78, Number 185, Part V, Tuesday, September 2013 for additional information.

Please see the FDA website for more information about the final rule and UDI compliance.

Compliance Dates for UDI Requirements. US FDA Website. Accessed 11 Oct 2018 at:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm

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