The label* of EVERY medical device (including all In Vitro Diagnostics) must have a UDI.

- Every device package (containing a fixed quantity of a version or model) must have a UDI.
- Any other approach is an exception or alternative from these requirements.

*Section 201(k) “label” as a display of written, printed, or graphic matter upon the immediate container of any article.

The most common reasons for a GTIN to change are:
- Change in the specifications, performance, size, or composition of the device to an extent greater than the specified limits (this includes the package itself)
- Change in quantity of a device package or addition of a new device package
- Change from a non-sterile package to a sterile package, or from a sterile package to a non-sterile package
- Re-labeling of the original labeler’s device
- Change labeling languages for different global markets
- Change in certification mark, e.g., CE Mark
- Change to outside package dimensions

Implementation (Compliance) Timeframes
- 2014: Class III and devices licensed under Public Health Services Act
- 2015: Class II/II implants and life-supporting/sustaining
- 2016: Class II items
- 2018: Class I and items that have not been assigned a class

For Direct Marking
- Compliance dates are extended by two years
- Except for Federal Drug and Administration Safety and Innovation Act (FDASIA) (Y2) devices—still 2015
- Direct marking only required for reusable devices that need to be “reprocessed” before reuse

Products & Inventories Existing Before Compliance Date
- Devices that are manufactured and labeled before their compliance date have an exception from the rule
  - The exception expires three years after the compliance date for that device
  - One year extension could be granted
  - Direct part marking compliance marks

FAQ
- If on the label, then needs to be included in the AIDC (Automatic Identification and Data Capture) technology
- Does not require any changes to currently used PIs