



UNIQUE DEVICE IDENTIFICATION (UDI)

UDI Systems Must Be Harmonized Globally

- Any UDI system which is developed should have as its purpose the improvement of patient safety. It should be standardized and globally harmonized. Regional variations should be avoided.

What the UDI System Should Contain

- The UDI tag should be limited to product identification, (manufacturer and product number). It should consist of: enterprise identifier number, designating manufacturer's name/address, part number, serial number, and lot number if appropriate. The UDI format should be standardized so that it can be used globally.
- The UDI database should contain product identification, but should not require serial number and lot number, in that they contain manufacturer proprietary information, except in the case where they are maintained by the local manufacturer. The amount of information contained in a product UDI database should be limited to that required to identify essential product characteristics needed for patient safety.

Placement of UDI

- Manufacturers should determine the placement of UDI, and the UDI should be applied to "finished devices," in conformity with current FDA regulations: i.e., systems, and/or components sold as "finished devices," accessories sold as "finished devices," as required by current FDA regulations, and other devices connected to the system (e.g. radiologic tables, printers, and PACS).

Refurbished and Remanufactured Devices

- The differences between "refurbished" and "remanufactured" devices need to be clearly defined and these devices must be treated differently. A "refurbished" medical device means having the same performance specifications as the original device. For "refurbished" medical devices, the original UDI should suffice. A "remanufactured" medical device means a device which has significantly changed safety or performance specifications, or intended use, of the original device. A new UDI should be placed on this device and tracked by the firm which performed the remanufacturing of the medical device in changing its specifications.

Software UDI

- Software that has been identified as a component that is sold as a finished medical device should be tracked by one UDI based on the name and version of the software. The UDI should be embedded into the software or user manuals, and accessible to the user.

Implementation Issues

- Manufacturers should have 24 months after the effective date of any regulations promulgated to implement a UDI system. Existing products in the market (i.e., in the installed base) should not require UDI. Instead, replacement of devices in the installed base should be done through attrition and obsolescence. Implementation should be on "high risk" devices first.
- An assessment should be performed by FDA to regularly and periodically monitor and measure the effectiveness of any UDI system.