FDA drops long-awaited Unique Device Identifier proposal

Mass Device

The FDA issues a proposed rule for a Unique Device Identifier system for tracking most medical devices, asking for public comments on implementing the long-awaited project.

The FDA's UDI label example: Product name, expiration date, reference and lot nos., manufacturer information, barcode, details and illustration.

The FDA released a proposed rule on its long-awaiting "unique device identifier" system for tracking and monitoring medical technology.

The rule would require most medical devices to carry labels with unique codes and scannable barcodes that will allow healthcare providers, regulators and the public at large to track the devices and monitor safety.

"The unique device identification system will help reduce medical errors, and will allow FDA, the healthcare community, and industry to more rapidly review and assess adverse event reports, identify problems relating to a particular device, and thereby allow for more rapid and effective corrective actions that focus sharply on the specific devices that are of concern," according to the proposal.

identifier-proposal