

# FDA launches medical device database: AccessGUDID

On May 4, 2015, the FDA launched the most recent component of its “[Unique Device Identification System](#),” or “UDI System,” first created in September of 2013 and required by the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law in July of 2012. ([See also §519\(f\) of the FD&CA or 21 U.S.C. § 360i](#)) The Global Unique Device Identification Database (Or GUDID, pronounced “Good ID”), is a searchable Web site containing a listing of all Unique Device Identifiers, or UDIs. The UDI system is designed to simplify the identification of certain medical devices used in the United States and regulated by the FDA.

Currently, manufacturers mark their medical devices using their own systems of lot, batch, catalogue, and/or model numbers. These numbers often mean very little to anyone but the manufacturing company, and as a result, it can be very difficult to identify individual devices. Similarly, confusing manufacturer-created marking schemes can make it incredibly difficult for hospitals or other organizations that purchase and implant these medical devices to file accurate and precise adverse event reports, or to alert the manufacturer to an issue. These issues with product identification also extend to the ability for individuals, health care providers and industry organizations to identify product classes, individual models and devices that may have significant issues.

The implementation of the UDI marking system is designed to solve these issues. UDIs will be used to specifically identify a device using both a plain text representation as well as a barcode or similar computer-readable format, and are designed to address a specific set of issues with current medical device marking and tracking systems.

1. **Reduce Medical Errors** - The link between UDIs and entries in the GUDID will allow physicians and health care providers the ability to rapidly and efficiently identify a device, its key attributes and its proper intended use. This can prevent errors related to the inadvertent misuse of a device when confused with devices of similar name or appearance.
2. **Simplification of Device Use Information into Data Systems** - Using UDIs, as opposed to the myriad of naming schemes used by device manufacturers today, will aid in proper inventory management, pre-surgery device identification, and proper device recommendations by physicians.
3. **More Rapid Identification of Medical Devices with Adverse Events** - With the now mandatory inclusion of UDIs within Adverse Event Reports submitted to the FDA by treating physicians, hospitals or device manufacturers, the FDA and manufacturers will be better able to aggregate, analyze and take appropriate measures to identify problem devices, identify risky procedures and develop proper solutions to minimize risks.
4. **Provide for More Rapid Recalls** - Similarly, the use of UDIs will allow manufacturers to better identify product batches or models that have defects, the patients in whom they have been implanted, and will facilitate more efficient and effective recalls, minimizing risks to affected patients.
5. **More Effective FDA Communications** - Currently, the FDA must rely on the previously described manufacturer-specific naming and marking schemes to identify medical devices when discussing them in Rules, Guidances or other publications. By instead referring to UDIs, the FDA can better and more accurately communicate new actions and policy to manufacturers, health care providers and patients.
6. **Better Identification of Similar Devices** - Though not called out by the FDA specifically, the new GUDID system also appears to provide a valuable resource for device manufacturers seeking to identify devices to fulfill the “substantial equivalence” requirements of 510(k) premarket notifications.

### The UDI

A UDI is composed of two parts:

- **Device Identifier (DI)** - A unique numeric or alphanumeric code specific to a device version or model.
- **Production Identifier(s) (PI)** - Numeric or alphanumeric codes that identify production information for a device and can include the following:
  - The lot or batch number;
  - The serial number;
  - The expiration date;
  - The date the device was manufactured;
  - For a Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) regulated as a device, the distinct identification code that allows the manufacturer to associate the HCT/P to the donor.

Therefore,  $UDI = DI + PI$ .

UDIs are created based on international standards for unique identification. Private organizations, called "Issuing Agencies", are accredited by the FDA to operate a system for the issuance of UDIs based on these standards.

### The Launch of GUDID

The GUDID launched on May 4th, in an early beta format, is the backbone that enables the entire UDI system to function. As the backbone of the UDI system, the GUDID is the go-to resource for health care providers, device manufacturers and patients when dealing with UDI-marked medical devices. Each GUDID entry provides the following information:

- **Device Identifier (DI) Information** - This is the most basic identifying information identifying the device. It includes the DI number, brand and model numbers, manufacturer and basic description.
- **Device Characteristics** - This is basic information about the device, and will vary based on the nature of the device identified. From prescription status, to MRI concerns, whether it is part of a kit, its proper storage and sterilization requirements, or if it is a biological product derived from human tissue, the Device Characteristics identify those aspects of the device most useful in identifying the device. This section will not necessarily contain safety information or warnings.
- **Device Status** - This section identifies whether the device is currently being distributed commercially, as well as the beginning and end dates of that distribution.
- **Alternative and Additional Identifiers** - This section describes whether the device bears any manufacturer-specific identifiers like lot, batch, model or category numbers or codes.
- **Customer Contact** - This section is designed to provide customers and consumers with a method of contacting the device company with questions or issues. However, in our brief survey of the site, few of the UDI entries had this section populated with manufacturer contact information.

While much of the information provided in the GUDID is similar or identical to the device's label contents, they serve slightly different purposes. While both are aimed at properly identifying the device, the GUDID information is not focused on patient education or warning. In later posts to this blog, we will discuss some of the exemptions to the UDI system requirements and corresponding GUDID listings.

[authorsTest](#)