Unique Device Identification (UDI) White Paper

Summary

This white paper has been produced to help readers understand the US Food and Drug Administration (FDA) final ruling on Unique Device Identification (UDI), describes how the ruling will impact the medical device industry and provides recommendations of how businesses can comply with its requirements.

Introduction

The Food and Drug Administration (FDA) has released a final ruling requiring that most medical devices distributed in the United States carry a unique device identifier, or UDI. It also applies to certain combination products that contain devices and those licensed under the Public Health Service (PHS).

A UDI system has the potential to improve the quality of information in medical device adverse event reports, which will help the FDA identify product problems more quickly, better target recalls and improve patient safety.

When fully implemented, a UDI system can:

1. Allow more accurate reporting, reviewing and analysis of adverse event reports, so that problem devices can be identified and corrected more quickly.

2. Reduce medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.

3. Enhance analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, and registries. A more robust post market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.

4. Provide a standardized identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.

5. Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and to prepare for medical emergencies.

6. Lead to the development of a medical device identification system that is recognized around the world.

What is a UDI?

A UDI is a unique numeric or alphanumeric code that consists of two parts:

1. A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and

2. A production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device

3. the lot or batch number within which a device was manufactured

4. the serial number of a specific device

5. the expiration date of a specific device

6. the date a specific device was manufactured

7. the distinct identification code required for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

The UDI ruling impacts manufacturers and distributors in two areas:

Labels: Compliant labels are required for all products and at all stages of packaging (i.e. from large cartons to individual packages)

Data: A set of data for each product and package sent to the FDA Global Unique Device Identification Database (GUDID) in the USA to be approved

ONLY WHEN YOU HAVE ACHIEVED THE ABOVE ARE YOU COMPLIANT. NON-COMPLIANT GOODS WILL NOT BE ALLOWED TO BE SOLD OR USED IN THE USA.

The FDA has declared that UDI requirements are likely to change, therefore medical device manufacturers will need to ensure that they remain UDI compliant over time.

Also, other countries are planning to release their own standards for identification of medical devices and products. It is likely that these standards will be primarily based on the FDA's standards with minor amendments to meet the specific regulatory requirements of each country.

Summary of compliance dates for the FDA UDI Requirements:

The FDA's final ruling for UDI compliance was published in September 2013.

Medical devices are defined in different classes, according to risk with regard to patient safety and need to be marked clearly according to these risk classes. Due to the extensive diversity of medical devices, a gradual risk-based approach to implementation has been agreed. As a rule, the FDA will normally

require compliance for Class III devices within one year after the final UDI publication, Class II medical devices in three years, and Class I medical devices up to five years. (NB: These classifications are the US device classifications, not the European classifications)

The table below outlines key compliance dates in the UDI final rule.

Compliance Date	Requirement
1 year after publication of the final rule (September 24, 2014)	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).
2 years after publication of the final rule (September 24, 2015)	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18.
	A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b).
	Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.

3 years after publication of the final rule (September 24, 2016)	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
	The labels and packages of class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b).
	Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
5 years after publication of the final rule (September 24, 2018)	A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
	The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20. Dates on the labels of all devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18.
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. Class I stand-alone software must provide its UDI as required by § 801.50(b).
7 years after publication of the final rule (September 24, 2020)	Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.

Compliance dates for all other provisions of the final rule. Except for the provisions listed above, FDA requires full compliance with the final rule as of the effective date that applies to the provision.

The trend towards global standards to ensure compliance

The FDA's final ruling is a major part of the trend towards common global standards in the medical device and products industry. In healthcare as in other industries, GS1 standards for identification and bar coding are recognized as the industry benchmark. In December 2013 GS1 became the first FDA-accredited UDI issuing agency.

GS1 Standards meet all the requirements of the UDI rule including:

1. Product identification at each level of the packaging hierarchy using the GS1 Global Trade

2. Item Number (GTIN)

3. Applicable bar code symbols

4. Applicable product data to be included in bar codes

5. All data that must be stored within the Global UDI Database specified by the FDA

The Challenge:

The challenge for Medical Device Manufacture's is how to comply with this FDA UDI final rule within the above timeframe, as failure to do so will have a severe business impact, as wrongly labelled products will not be accepted.

The size of the problem facing Medical Device Manufacturers varies. Costs of compliance will be greater for organizations that manufacture in multiple countries and use different enterprise reporting and labelling systems.

For small and medium size enterprises (SMEs), which constitute the majority of suppliers, UDI compliance is projected to be costly not just in terms of software and labelling system upgrades, but also in terms of management time and attention understanding and administering ever changing regulatory requirements.

The Solution:

For the vast majority of medical manufacturers who need to demonstrate UDI compliance, a cloud based UDI service may be the most viable and cost effective way forward as it will avoid costly in house upgrades.

The UDI solution also includes all the necessary components needed, such as pouch/bag sealers, coders, labelers or scanners.

The UDI Service Compliance solution gives users the opportunity to realize the following benefits:

1. Significantly reduced implementation costs

2. Reduced costs of keeping up with GS1, FDA and other standards

3. Reduced costs associated with product recalls and non –compliance

4. Elimination of the costs associated with manual processes and errors

5. Improved information for management and audit purposes.

How the OK Supersealer MBS can help with the UDI requirements

With the necessary components required for the UDI requirements, OK International can recommend the medical band sealer, the OK Supersealer MBS with the IJet Coder for your packaging solution(s). This combination results in great traceability for the UDI/GS1 requirements.

How the IJet Coder works – features and benefits
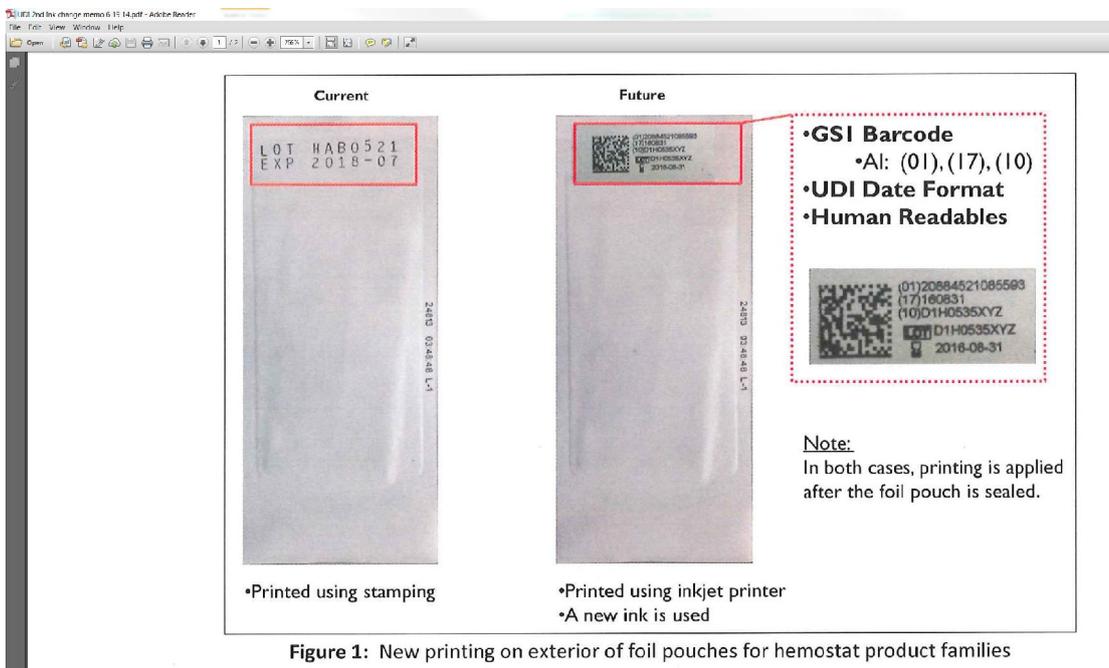
Figure 1: New printing on exterior of foil pouches for hemostat product families