U.S. FDA Extends UDI Labeling Enforcement Date for Class I Medical Devices

On July 1, 2020 the U.S. Food and Drug Administration issued a new guidance document indicating that they do not intend to enforce standard date formatting, Unique Device Identification (UDI) labeling, and Global Unique Device Identification (GUDID) data submission requirements for Class I and Unclassified medical devices that are not implanted, life sustaining, or life supporting before September 24, 2022.

This marks the second time that the FDA has indicated enforcement discretion for the date format, UDI, and GUDID data submission requirements for Class I and Unclassified medical devices, previously extending enforcement date until September 24, 2020.

The FDA also indicated that they do not intend to enforce the direct mark requirements for Class I and Unclassified devices that are not implanted, life sustaining, or life supporting before September 24, 2022. The guidance document also includes information on the FDA's direct marking enforcement policy for certain medical devices that were manufactured and labeled before their direct marking compliance date, but remain in inventory.

Background
In September 2013, the U.S. Food and Drug Administration (FDA) rolled out the Unique Device Identification (UDI) labeling requirements for most medical devices. Class III medical devices (e.g. high risk medical devices) were the first group of medical devices required to list a UDI and meet the corresponding date formatting and GUDID data submission requirements. Class I and Unclassified medical devices that are not implanted, life supporting, or life sustaining are the last groups of medical devices that need to meet the labeling requirements.

Click to view the guidance
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and

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For over 35 years, Bureau Veritas has worked successfully with top retailers and manufacturers around the world to help them better manage risk and regulatory compliance. If you have any questions, please contact your customer service representative or email: cps.info@bureauveritas.com.

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