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American Dental Association

Technical Report No. 1081

FDA's Unique Device Identification (UDI) Program for Dental Devices and Biologics Regulated as Medical Devices

ADA American Dental Association®

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AMERICAN DENTAL ASSOCIATION TECHNICAL REPORT NO. 1081 FOR FDA'S UNIQUE DEVICE IDENTIFICATION (UDI) PROGRAM FOR DENTAL DEVICES AND BIOLOGICS REGULATED AS MEDICAL DEVICES

The Council on Dental Practice of the American Dental Association has approved American Dental Association Technical Report No. 1081 for FDAs Unique Device Identification (UDI) Program for Dental Devices and Biologics Regulated as Medical Devices. Working Groups of the ADA Standards Committee on Dental Informatics (SCDI) formulate this and other specifications and technical reports for the application of information technology and other electronic technologies to dentistry's clinical and administrative operations. The ADA SCDI has representation from appropriate interests in the United States in the standardization of information technology and other electronic technologies used in dental practice. The ADA SCDI confirmed approval of ADA Technical Report No. 1081 on July 10, 2015.

The ADA Standards Committee on Dental Informatics thanks the members of Working Group 11.8 on Track and Trace for Implantable Devices and the organizations with which they were affiliated at the time the specification was developed:
Mohamednazir Harunani (chairman), Academy of General Dentistry, private practice, Rockford, IL;
Leslie Tompkins Steen, US FDA Center for Devices and Radiological Health, Silver Spring, MD; and
Kristy Vogt, American Dental Association, Chicago, IL.

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FOREWORD

(This foreword does not form a part of Proposed American Dental Association Technical Report No. 1081 for FDA's Unique Device Identification (UDI) Program for Dental Devices and Biologics Regulated as Medical Devices).

In 1992, there was interest in the standardization of clinical information systems related to electronic technology in the dental environment. After evaluating current informatics activities, a Task Group of the ANSI Accredited Standards Committee MD156 (ASC MD156) was created by the ADA to initiate the development of technical reports, guidelines, and standards on electronic technologies used in dental practice. In 1999, the ADA established the ADA Standards Committee on Dental Informatics (SCDI). The ADA SCDI is currently the group that reviews and approves proposed American National Standards (ANSI approved) and technical reports developed by the standards committee's working groups. The ADA became an ANSI accredited standards organization in 2000.

The scope of the ADA SCDI is:

> *"The ADA SCDI shall develop informatics standards, specifications, technical reports and guidelines and interact with other entities involved in the development of health informatics standards aimed at implementation across the dental profession."*

FDA's UDI Ruling and Guidance

The *Unique Device Identification* (UDI) project was undertaken by the ADA-SCDI, with Dr. M. Harunani being named as the chair, to address the FDA's recent UDI rule and to offer their expertise, guidance and best practices on implementing automatic identification and data capture technologies and their application in dentistry.

This technical report was prepared by SCDI Working Group 11.8. The SCDI Working Group chairman is Mohamednazir Harunani. SCDI Working Group 11.8 prepared this report at the request of SCDI Subcommittee on Clinical Informatics.

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SUMMARY

The Food and Drug Administration (FDA) has issued a rule to establish a system to adequately identify devices through distribution. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI will be required to be directly marked on the device itself, if the device is intended to be used more than once and intended to be reprocessed before each use

SCOPE

Once it was recognized that this rule was going to take effect, practitioners needed to have an understanding of this rule and what it will entail as it is required to go into practice, from a clinician side. The manufacture chain and responsibilities have been clearly identified by the FDA, but the clinical use has not; and thus that was determined to be the main focus of this paper. This paper covers the UDI Rule (78 FR 58786) and device marking regulations in 21 CFR 801.45. It does not cover the regulations for medical device tracking found in 21 CFR 821. There is no tracking requirement within the UDI rule.

Background

Each year, the FDA receives several hundred thousand medical device reports of suspected device-associated deaths, serious injuries and malfunctions. The ideal outcome is that we have an end to end tracking system that is transparent. Mandatory reporters (i.e., manufacturers, device user facilities, and importers) are required to submit certain types of reports for adverse events and product problems to the FDA about medical devices. In addition, the FDA also encourages health care professionals, patients, caregivers and consumers to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as use errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety. The FDA has now mandated a rule that requires labelers to affix a UDI, in plain-text and AIDC format, to the label of every medical device, unless excepted, and to submit device data to the Global Unique Device Identification Database (GUDID). There are several methods of recording the device ID. They can be:

Radio-frequency identification (RFID) – the wireless use of electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects. The tags contain electronically stored information. Some tags are powered by electromagnetic induction from magnetic fields produced near the reader. Some types collect energy from the interrogating radio waves and act as a passive transponder. Other types have a local power source such as a battery and may operate at hundreds of meters from the reader. Unlike a barcode, the tag does not necessarily need to be within line of sight of the reader, and may be embedded in the tracked object.

Matrix (2D) barcode – a two-dimensional way to represent information similar to a linear barcode, but can represent more data.

Linear Barcodes – "one dimensional" barcode that is made up of lines and spaces of various widths. These codes can be issued by GS1, ICCBBA, or HIBBCC.

GUDID Sample: