THE VISION COUNCIL

SEPTEMBER 24, 2018 IS APPROACHING!

UDI GUIDANCE FOR THE S&R, E&A AND LOW VISION DIVISONS

WHAT IS THE UDI SYSTEM?

The Unique Device Identification system, known as the UDI, will be used to identify and trace medical devices through distribution and use. Labels of medical devices will include a UDI in human and machine readable forms, and UDI labelers must submit information into the FDA's Global Unique Identifier Database ("GUDID"). For more UDI info, see **https://www.thevisioncouncil.org/sites/default/files/members/VCUniqueDeviceIDGuide2013.pdf**

WHY IS SEPTEMBER 24, 2018 IMPORTANT?

Compliance with the UDI system for Class I medical devices will be required as of that date. This includes both the labeling requirement and the GUDID reporting requirement.

WHERE DO I GET UDIS?

The FDI has certified three UDI issuing agencies. Their contact information can be found at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm**

DO I HAVE TO GET UDIS FROM UDI ISSUING AGENCIES, OR CAN I USE MY UPC AS A UDI?

Good news. The UDI regulations authorize the use of a UPC as a UDI for Class 1 medical devices sold at retail, which would obviate the need to procure UDIs from a certified UDI issuing agency. The Vision Council foresees that its E&A, S&R and Low Vision divisions members will be able to take advantage of using a UPC as the UDI.

IF I USE MY UPC, DO I STILL HAVE TO REPORT PRODUCT INFORMATION INTO THE GUDID?

Yes. Companies involved with Class I medical devices must populate the GUDID, even if they use a UPC as a UDI. UDI Labelers only need to report their "DI" (device information) portion of the UDI into GUDID. The DI is the mandatory fixed portion of the UDI that identifies the identity of the labeler and the specific version or model of the device. Different versions or models require different DIs, and thus different UDIs.

DO I NEED A GUDID ACCOUNT?

Yes. The GUDID process is complicated. First, you need to create an account, which you do at **http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416113.htm**

Then you need to decide how you will report into the GUDID. The GUDID allows users two reporting options. One is a web interface, which allows the user to enter the required data on a one at a time basis. This option should appeal to users with few UDIs to report. The second option is an HL7 SPI option for XML files. This option should be used by reporters with many UDIs to report.

We recommend that you set up and test whichever reporting approach you adopt well in advance of the September 24, 2018 deadline. The use of third-party reporters is allowed also.

QUESTIONS – CONTACT THE FOLLOWING:

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