THE GUIDE TO SUCCEEDING WITH UDI COMPLIANCE

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With another big UDI deadline fast approaching on September 24th, 2015, you may be more confused than ever on what is required to have you fully compliant with the FDA. This handy little guide written by Zebra Technologies will walk you through each of the criteria below.

STEP 1
Apply for Unique Device Identifiers

Unique device identifiers are supplied directly from three FDA-approved organizations - GS1, the HIBCC, or the ICCBBA and each of your Class III medical devices should already have them in place. Starting on September 24th, 2015, your packaging for class III devices and any associated software (and its packaging) also needs to have unique identifiers as well. This includes cardboard shipping boxes and shrink-wrapped pallets, sterile internal packaging and anything else your devices are stored in.

STEP 2
Properly Design UDI Labels

Each UDI must contain the device identifier, production information (device name, serial numbers, batch numbers, etc.), and any applicable expiration dates. While it may be a challenge to fit all of this information on smaller labels, it must be able to be clearly read by human eyes and a digital device. Many companies will have to redesign their labels to remain in compliance.

STEP 3
Submit to the GUDID Database

Once you have collected the required information by the FDA, it needs to be submitted to the GUDID for all Class III devices by September 24th, 2015 (9/2016 for class II and 9/2018 for class I). This can be completed manually through the FDA's web interface or in spreadsheet format through an HL7 software interface.

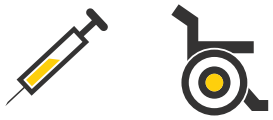
STEP 4
Print and Affix UDI Labels

While there are a number of barcode options available from a variety of printer types, remember that labels have to be at least "B" quality or better to meet FDA standards. Labels must be placed directly onto each device in a highly visible area, although the identifier can be printed directly onto packaging or the device itself.

Class I
Generally safe, non-controlled devices

Bandages | Bedpan | Gloves

Class II
Non-evasive controlled devices



Surgical Needle | Powered Wheelchair

Class III
Highly regulated life support devices

Pacemaker | Heart Valve

For a free demo of our UDI submission solution e-mail us at **UDI@coridian.com,** call **952-227-9129,** or visit **http://www.coridian.com/Coridian-UDI-Compliance-Solutions**.