DJO® POWERING MOTION™

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Determining UDI Information from Product Labeling without UDI Barcode

Dear End User:

In line with FDA's requirements for including Unique Device Identification (UDI) information on medical device labeling and products, DJO Surgical has been meeting this requirement since Q4 2015. This compliance includes barcode labeling and submitting required information to FDA's GUDID system.

However, there may be some products currently in distribution that were put into the market prior to the initiation of the UDI process. In line with FDA's communication, UDI-A170001, the following information provides an overview on how to determine the UDI information from the labeling that does not have the barcode.

The DJO Surgical UDI information includes the following elements:

- Product Brand
- Device part number
- Description
- Device lot number
- Expiration Date
- Single Use

As noted on the following page, this same information can be determined from the product package.

If you have any questions, or require additional instructions, please contact Teffany Hutto, Manager, Regulatory Affairs at 512-834-6255 or at teffany.hutto@djoglobal.com

Outer Box Labeling