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Comment from Health Watch USA et al

Posted by the **Food and Drug Administration** on Dec 19, 2019

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Enclosed are comments from 15 non-profit advocacy organizations regarding tracking and preserving the medical device's Unique Device Indicator records, along with information regarding the distributor and prescribing physician.

The UDI is a code which identifies the device. However, in the event the device is removed from the patient or the patient dies the records of the UDI may be deleted. In addition, there are no requirements for medical device implants to directly contain the UDI.

The result is after a severe complication occurs with an implant, the FDA does not require retention of UDI records.

We feel this is a lapse in post market surveillance of devices, which may delay the epidemiological detection of design flaws and the identification of counterfeit devices which adversely affects patient safety.

Full comments along with additional recommendations are contained in the enclosed file.

Attachments 1

Comment from Health Watch USA et al

More Information

Download (https://downloads.regulations.gov/FDA-2015-D-2245-0023/attachment_1.pdf)

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