Reprocessing of Single Use Medical Devices

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Background

The Food and Drug Administration (FDA) requires that certain medical devices once intended for single use only, can be approved for re-use as described in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

MDUFMA requires that reprocessors of certain types of previously-cleared reprocessed single use devices (SUDs) submit supplemental data to the FDA. Following submission of that data, the FDA has determined that supplemental cleaning, sterility, and functionality validation data were needed in order to determine if these reprocessed devices could continue to be legally marketed. As it now stands, the reprocessing of former single use Class I and II medical devices is legally permissible in the United States. Approximately 1,800 models of reprocessed SUDs require validation data under MDUFMA.

In addition to the complex procedures required to obtain approval of the reuse of medical devices, MDUFMA further stipulates that these reprocessed devices prominently and conspicuously display the name, abbreviation, or symbol of the re-processor on the device itself, or on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device.

Position

After studying the FDA's findings and outcomes, the Association for Professionals in Infection Control and Epidemiology (APIC) is in support of the FDA's requirements for devices meeting the criteria for reprocessing as described in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

Action

APIC urges members to regularly review their organizations' policies and procedures involving third party reprocessors to ensure all documented quality and safety agreements are current and comply with FDA's requirements for both MDUFMA and reporting of any adverse events.

To access the Medical Device User Fee and Modernization Act of 2002, Public Law 107-250, click on the following link http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ250.107