

Assessment of Regulatory Compliance Issues Involving Reprocessing of Single-Use Devices in the United States

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Summary

Reuse of single-use devices (SUDs) in hospitals is a clinical problem worldwide. The U.S. government started regulating SUD reuse under the “Medical Device User Fee and Modernization Act (MDUFMA)” in 2002. The U.S. Food and Drug Administration (FDA) requires hospitals and SUD reprocessors to comply with the MDUFMA and with the same regulations for medical devices that the manufacturers of the original SUDs must comply with. The FDA also requires hospitals and SUD reprocessors to submit validation data ensuring that the reprocessed SUDs are substantially equivalent to the original device, as well as to comply with Quality System Regulation (QSR). In this study, we investigated what problems occur when using reprocessed SUDs, and whether appropriate regulations are in place, in order to examine whether U.S. hospitals and reprocessors are having difficulty complying with QSR.

Six issues in four categories in the use of reprocessed SUDs were examined: evaluations of device safety and effectiveness; regulations on reprocessed SUDs as medical devices and product liability in legal affairs; informed consent in medical ethics; and reimbursement price in the healthcare insurance regime. We found that the device safety, device effectiveness and medical device regulations on reprocessed SUDs are controlled under MDUFMA. However, MDUFMA does not regulate product liability, informed consent or insurance reimbursement.

We also analyzed how SUD reprocessors comply with QSR regulations, and found that they have difficulty complying with the regulations on purchasing control, design changes and dealing with OEM product recall, because SUD reprocessors do not have access to all the original device information, and there is a time lag between OEM actions on the original device and reprocessors' acquisition of information on changes or recall of the original SUD.

Key words

Single-Use Device (SUD), Reprocessing, 510(k), Quality System Regulation (QSR), Recall, Design change, U.S. Food and Drug Administration (FDA)