



Reprocessing Devices Labeled as “Single-Use

Undisputed Facts About Reprocessing

- Single-use device reprocessing is regulated and controlled by the U.S. Food and Drug Administration (FDA). (<http://www.fda.gov/cdrh/mdufma/faqs.html#19>)
- Single-use devices are allowed to be reprocessed in accordance U.S. federal law. (<http://www.fda.gov/cdrh/comp/guidance/1168.pdf>)
- The FDA requires reprocessed single-use devices to be thoroughly cleaned, tested, and sterilized in such a manner as to provide a reasonable assurance to ensure the safety and effectiveness of the devices. (<http://www.fda.gov/cdrh/ode/guidance/1216.pdf>).
- Reprocessors of single-use devices are required to comply with the same medical device regulations as original manufactures, where applicable.
- Reprocessors must, like all other device manufacturers, comply with all of the applicable requirements of the Food, Drug, and Cosmetic Act (FDCA). Specifically, reprocessors are subject to:
 - establishment registration and medical device listing
 - medical device reporting
 - medical device tracking
 - reports of corrections and removals
 - the quality system regulation (“QSR”)
 - heightened labeling requirements
 - premarket review of their devices by FDA, unless the agency has, by regulation, declared the device to be exempt from premarket requirements. 21 U.S.C. § 360(k)
- New devices fail or malfunction from time to time, as do reprocessed devices. See FDA’s Manufacturer and User Facility Device Experience database, which can be found at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>
- Properly reprocessed single-use devices are as safe and effective as new devices. See 21 U.S.C. § 360(k) and FDA’s Manufacturer and User Facility Device Experience database, which can be found at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>.
- Many professional clinical organizations have responded positively to the concept of Reprocessing. These include:
 - American College of Cardiology
 - American Association of Orthopedic Surgeons
 - Association of periOperative Registered Nurses
 - American Gastroenterological Association
 - International Association of Healthcare Central Service Material Management
 - American Society for Healthcare Central Services Professionals
 - Association for the Advancement of Medical Instrumentation
 - North American Society of Pacing and Electrophysiology
 - Association of Professionals in Infection Control and Epidemiology
 - American Hospital Association