



FDA Inspection Finds Medical Device Reprocessing Facility 100 Percent Compliant

The Food and Drug Administration found ReNu Medical, a medical device reprocessing facility, 100 percent compliant in a recent inspection. The facility was also not issued a 483 report for the second inspection in a row.

Everett, WA (PRWEB) October 23, 2007 - ReNu Medical announced that its medical device reprocessing facility in Everett, Washington, was recently found 100 percent compliant by the Food and Drug Administration (FDA). ReNu (www.renumedical.com) continues its long standing focus on patient safety and cost savings while maintaining the highest levels of compliance with FDA guidelines and standards.

Chief Operations Officer Bruce Pierson said that the latest FDA audit was the second consecutive inspection in which zero deficiencies were found at the facility.

"I am extremely pleased with the FDA's results. Not being issued a 483 from the FDA for the second inspection in a row demonstrates our quality commitment that has to date been unmatched," Pierson said. "ReNu is uncompromising in our attention to the highest product quality and safety as substantiated by the results of both the previous and latest FDA inspections.

"ReNu Medical's normal high quality operating practices and standards are extremely difficult for other reprocessors and sterilizers to meet, much less beat, and ReNu's High Level Disinfection (HLD) is 100 percent non toxic and environmentally friendly."

The 483 report, issued after completing a thorough and detailed inspection, is a standard FDA operating procedure outlining any and all deficiencies the FDA believes needs changed to assure the safest products to the public. It provides the inspected facility management a clear direction of what must be corrected or changed. These reports are available through the FDA via the Freedom of Information Act.

"With the critical operating insights that the FDA's 483 report provides, ReNu recommends that as part of any hospital's current contract status or prior to a



hospital contracting with any medical device reprocessing company, hospitals inspect the reprocessor's facilities and review the Establishment Inspection Report (EIR) of each 483, which details any and all deficiencies required to improve or correct quality and safety issues," said Randy Long, CEO. "Two key problems that constantly challenge hospitals are out of control supply costs and managing ongoing waste reduction initiatives. ReNu delivers the most cost-effective, non-toxic solutions addressing both problems with absolutely no capital investment by the hospital. It's a win-win for the hospital and the environment."

About ReNu Medical

ReNu Medical is a leading reprocessor of non-invasive single use medical devices (SUD's). ReNu's unique services focus on providing the safest product for the patient, reducing medical waste and significantly reducing supply costs by maximizing available savings.

ReNu's focus on non- and semi-critical devices provides a significant source of cost savings with very little associated risk. High Level Disinfection (HLD) offers significant cost saving advantages over sterilization methods. High-Level Disinfection technology is 100 percent non toxic, environmentally friendly and a safe gentle alternative for ReNu's target devices. HLD offers twice the lifespan and double the savings of toxic Ethylene Oxide Gas (EtO) utilized by sterilization reprocessors. No harmful air emissions are released into the environment and no chemical residue is left on the device.

HLD is supported by the CDC, APIC and other healthcare organizations. ReNu Medical is a supporter and Champion of Hospitals for a Healthy Environment. We recommend you visit their website (www.h2e-online.org) to learn more about how to reduce hospital medical waste.

For more information on ReNu Medical's recent FDA inspection, or for more information on medical device reprocessing, visit www.renumedical.com.

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