

ReNu Medical Alerts Hospitals to Misuse of FDA 5-10k's

ReNu Medical has the legal 5-10k's to high-level disinfect (HLD) reprocess non and semi critical (single use) medical devices for US hospitals.

Everett, WA May 26, 2005...“It's misleading; the FDA website lists only the company or individual who originally filed and was issued a 5-10k. Much like the listing of a Patent and/or Trademark, the websites do not publish the selling, purchase or assignment of the original document. Unless a medical device reprocessing company is honest enough to mention this fact, a healthcare facility would never know they could be held liable for illegally marketed HLD reprocessed medical devices they receive from a vendor,” said Loren Timmons, VP Marketing and Business Development at ReNu Medical.

In 2002, ReNu Medical purchased and was assigned several FDA 5-10k's from Hygia Health Services located in Birmingham, Alabama. On that date according to the FDA, Hygia Health Services lost all rights to market reprocessed single use medical devices specific to those 5-10k numbers.

“A 5-10k is a company's “license” to legally market reprocessed medical devices. It is important to understand that 5-10k's can be bought and sold on the open market.

According to the FDA, they can only be used (marketed) by the company it is assigned to. This means, once a company sells or assigns their 5-10k to another company, they lose all rights to legally market reprocessed medical devices specific to that 5-10k,” said Randy Long, CEO at ReNu Medical. “ReNu's 5-10k documentation was re-verified in January 2005 during our last FDA inspection.”

“Patient safety and FDA compliance is the cornerstone of ReNu Medical. Not having the FDA 5-10k for high-level disinfection reprocessing of single use medical devices is like driving a car on the wrong side of the road; it is simply a matter of time before you get caught: or worse kill someone,” said Bruce Pierson, Chief Operations Officer at ReNu Medical. “Information published on the FDA website may not be current or correct. Hospitals need to understand they have the final liability and risk of using such information.”

About ReNu Medical:

ReNu Medical is the leading HLD 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 unique focus on non and semi critical devices provides a significant source of cost savings with very little associated risk. These devices go ON the body not IN the body. High Level Disinfection (HLD) offers significant cost saving advantages over sterilization methods.

For example, ReNu's non-toxic method of HLD has the proven ability to turn an individual medical device 2-3 times more than a sterilizing reprocessor that equates to 2-3 times the cost savings. Additionally, with our quick turn around time, two weeks compared to 8-12 weeks, less inventory is required thus saving you even more money. Finally, ReNu has the proven lowest discard rate in the industry (less than 10% on average) allowing you to get more devices back. These advantages offer significant savings far above other reprocessors.

High-Level Disinfection technology is 100% non-toxic, environmentally friendly and a safe gentle alternative



for the non and semi critical devices. HLD offers twice the life span and double the saving of toxic Ethylene Oxide Gas (EtO) utilized by sterilization reprocessor's. No harmful air emissions are released into the environment and no chemical residue is left on the device. The CDC, APIC, and other healthcare organizations support HLD.

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.

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