The FDA was created to protect the consumer (patients AND healthcare providers) from defective, negligent or misrepresented health products that could pose serious risk to the end users health – or life. Without GUDID device identification, there is no thorough tracking compliance through the FDA. This puts you at risk and potentially liable.

How it does this:
1. By requiring every manufacturer of medical devices to pay annual registration fees (thousands of dollars annually)
2. By imposing strict documentation and quality control standards called GMP, which the FDA monitors by on-site inspection, audits, and mandatory safety reporting.

Second-hand resellers that are not a manufacturer or are not authorized by a manufacturer are not currently accountable to FDA or to any quality standard monitoring system, nor can the FDA track these devices and their history.

Because of traceability concerns like these, the FDA started GUDID. It is a new rule created to help the FDA monitor ongoing safety and efficacy of marketed medical devices. The “Good ID” is a unique device identification number which is mandatory to be on every device sold after September 2016 by every monitored, regulated device manufacturer (or refurbisher) that is compliant with the rule. With this system, FDA is trying for more accurate reporting, analysis, and of course, corrections related to adverse events in the field. This ongoing, long term analysis data also helps manufacturers correct software bugs and improve or prevent other issues for devices in the field.

The risk of adverse events is of particular importance as used devices get older especially if they are not factory maintained. The FDA requires critical tools and components must be calibrated on a regular schedule to assure performance is maintained to specifications. Decompression machines should be calibrated annually. The FDA is aware and is continually implementing new measures to police, like GUDID.

There are serious challenges and risks third-party (unauthorized) resellers create when attempting to restore or repair devices to their original specifications having no training, factory support or proprietary knowledge. Therefore, possible public health issues can easily arise from these activities.

Who is at risk?
Public health issues obviously put the patient at risk of injury or even death when medical products don’t perform according to specification. But serious risk passes to the healthcare provider when something goes wrong because of several areas for exposure:
1. Used equipment re-sellers are not required to carry expensive product liability insurance, so you are left to shoulder that risk alone.
2. Manufacturers product liability insurance policies become immediately VOID after any unauthorized third party product tampering.
3. Savvy lawyers have won hundreds of millions in malpractice liability cases by emphasizing to juries that healthcare greed and unwillingness to properly maintain equipment caused a patient injury.

Saving a few thousand dollars on a second-hand device that lacks an absolute credible service history, could be a practice damaging mistake.

Without GUDID device identification, there is no thorough device tracking compliance through the FDA. Federal enforcement will only become more and more aggressive. Which likely explains why recently the FDA clarified its position on their enforcement powers: under section 502(t)(2) and 301(q)(1)(b) of the FD&C Act (21 U.S.C.), potential enforcement actions for violations of UDI requirements include seizure, injunction and civil and criminal penalties.