In a recent study published in the Archives of Internal Medicine the authors found that 71 percent of medical devices were approved through the FDA's less-rigorous 510(k) process. Most of the medical devices recalled in the FDA's highest-risk recall category (a risk of serious injury or death) were cleared for sale through the weaker of the agency's two regulatory schemes, according to a study published in the Archives of Internal Medicine.

The authors reviewed 113 medical device recalls between 2005 and 2009 that the FDA classified as posing the highest risk of serious health problems or death and determined what regulatory processes the devices had gone through. Less than twenty percent (20%) of the recalled devices had been approved through the more stringent "Premarket Approval" (PMA) process, which requires clinical testing and trials. Seventy-one percent of the recalled medical devices went through the 510(k) process, which requires that the device be substantially equivalent to a "predicate" device already on the market.

The researchers wrote that the 510(k) process "was specifically intended for devices with less need for scientific scrutiny, such as surgical gloves and hearing aids." But medical devices have become more complex. The authors further stated that "in an era of aggressive deregulation," the process was changed to allow medical devices with different materials and mechanisms to serve as predicate devices, if they had similar safety profiles, so other 510(k) approved devices served as predicate devices. The authors acknowledged that even the more stringent approval process was lacking. The stated "while even the more rigorous PMA criteria for device approval are often scientifically inadequate to ensure patient safety, PMA standards are clearly superior to 510(k) standards."

The authors' recommendations included requiring life-saving and life-sustaining devices to go through the more stringent PMA process and expanding the FDA's authority to inspect the manufacturing of 510(k) devices and to require post-market surveillance.

It seems that the 510(k) is simply a free pass for medical device manufactures to place dangerous devices on the market and it appears to regularly result in medical devices being recalled due to the risk of serious injury or death.