FDA ISSUES PROPOSAL TO IMPROVE THE QUALITY OF AEDS

The U.S. Food and Drug Administration has issued a proposed order aimed at helping manufacturers improve the quality and reliability of automated external defibrillators (AEDs). The proposed order, if finalized, will require manufacturers of these life-saving devices to submit pre-market approval (PMA) applications. Although these devices have saved lives over the years, the FDA has received approximately 45,000 adverse event reports between 2005 and 2012 associated with the failure of these devices. Manufacturers have also conducted dozens of recalls. The problems the FDA is seeing with AEDs are preventable and correctable. The most common issues involve the design and manufacture of the devices and inadequate control of components purchased from other suppliers. For more information go to:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm345062.htm