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USFDA springs to action to improve AEDs reliability

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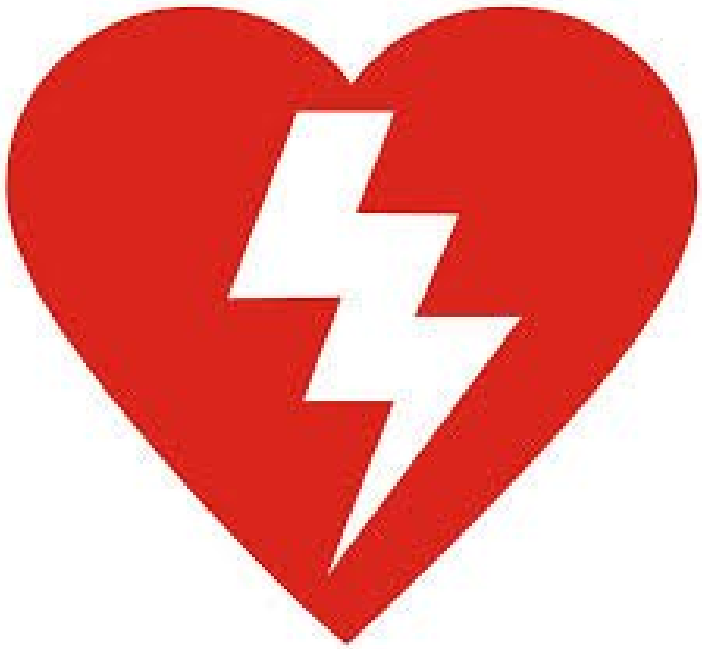

Automated external defibrillators are portable, electronic medical devices that automatically sense potentially life-threatening cardiac arrhythmias and either automatically deliver or advise the user to deliver electrical stimulation to re-establish normal heart rhythms.

They are often stored in public locations for use in an emergency and, while they can be lifesaving, there has been a history of malfunction issues.

The FDA issued a final order that will require AED manufacturers to submit premarket approval applications (PMAs), which undergo a more rigorous review than what was required to market these devices in the past.

The agency's strengthened review will focus on the critical requirements needed to ensure the safety and reliability of AEDs and their necessary accessories, including batteries, pad electrodes, adapters and hardware keys for pediatric use.

"Automated external defibrillators save lives," said Mr William Maisel, deputy director for science, chief scientist and acting director of the office of device evaluation in the FDA's Center for Devices and Radiological Health. "These changes to the way these devices are reviewed will allow us to more closely monitor how they are designed and manufactured. This will go a long way towards correcting long-standing problems and ultimately improving the reliability of these devices."

From January 2005 through September 2014, the FDA received approximately 72,000 medical device reports associated with the failure of these devices.

Since 2005, manufacturers have conducted 111 recalls, affecting more than two million AEDs.

The problems associated with many of these recalls and reports included design and manufacturing issues, such as inadequate control of components purchased from other suppliers.

By requiring premarket approval for these devices, the FDA will receive important information about an AED manufacturer's quality systems information.

The FDA will also conduct inspections of manufacturers' facilities prior to approval.

After approval, manufacturers will be required to submit to the FDA any changes made to the devices that affect safety or effectiveness, and annual reports on device performance.

Given the importance of these devices in emergency situations, AEDs currently on the market will remain available while manufacturers work to meet the new PMA requirements.

The FDA does not intend to enforce the PMA requirement for AEDs until July 29, 2016, as long as manufacturers notify the FDA of their intent to file a PMA by April 29, 2015.

The FDA does not intend to enforce the PMA requirement for currently marketed, necessary AED accessories until January 29, 2020.

The Food and Drug Administration Safety and Innovation Act calls for the FDA to publish proposed and final orders to reclassify or call for PMAs for pre-amendments devices.

The FDA's Circulatory System Devices Panel recommended that AEDs remain Class III medical devices and require PMAs.

The FDA originally issued a proposed order in March 2013 calling for PMAs to ensure the appropriate regulation of Class III pre-amendments devices.