FDA aims to change the way it monitors safety of defibrillators

March 26 2013, by Karen Kaplan

Defibrillators are supposed to save lives by shocking a patient's heart back into a normal rhythm, but they have malfunctioned in about 45,000 cases since 2005, according to the Food and Drug Administration. So on Friday, the FDA proposed new rules aimed at ensuring that the potentially life-saving devices work properly when they're needed.

The FDA's plan is to require manufacturers of automated external defibrillators, or AEDs, to submit applications for pre-market approval, according to this announcement. That would allow the agency to "more closely monitor how these devices are designed and manufactured," according to the FDA announcement.

AEDs are portable devices used to treat victims of sudden cardiac arrest, a condition in which "the heart suddenly and unexpectedly stops beating," depriving the brain and other vital organs of blood, according to the National Heart, Lung and Blood Institute. Patients usually die if they're not treated within a matter of minutes - for each one-minute delay, the patient's odds of survival drop by 10 percent, the institute says.

AEDs help by sending an electric shock to the heart via sensors attached to the patient's chest. Before the shock is delivered, the sensors send information to a computer in the AED to figure out whether an electric shock would help. If the computer decides that it will, a voice prompt tells the operator what to do, the institute's website says. If all goes according to plan, the patient's heart will resume beating properly.

The problems with AEDs are varied. In one case, a defibrillator made by Defibtech was recalled to fix a software problem that could cancel the shock. In another case, Philips Healthcare recalled thousands of its HeartStart units because a faulty memory chip was rendering the devices inoperable. In yet another case, a faulty component prompted a recall of AEDs made by Cardiac Science.

These problems are "preventable and correctable," according to the FDA announcement.

"Automated external defibrillators save lives," Dr. William Maisel, chief scientist at the FDA's Center for Devices and Radiological Health, said in a statement. "However, the agency is concerned about the number of recalls and manufacturing problems that have been associated with these devices and we're committed to working with manufacturers to address these issues."

Though the problem with defibrillators is serious, the FDA has judged that the public is better off keeping them in use while the issues are resolved rather than taking them off the market altogether.

The proposed rules came from the agency's Circulatory System Devices Panel. If approved after a 90-day public comment period, the FDA plans to "exercise enforcement discretion" for 18 months, it said.