

Premarket Approval of Medical Devices (0910-0231)

Change Request 83C

August 27, 2014

FDA is submitting this nonmaterial/nonsubstantive change request (83c) in order to increase the burden estimate for OMB control number 0910-0231, Premarket Approval of Medical Devices, by 33.5 responses and 22,378 hours. This request is being made to reflect the burden shift between the Premarket Notification (510(k)) ICR (0910-0120) and the Premarket Approval of Medical Devices ICR (0910-0231) due to the classification of medical devices under section 515(i) of the Federal Food, Drug, and Cosmetic Act.

Automated external defibrillators systems (AEDs) (including the AED device and its accessories (i.e., pad electrodes, batteries, and adapters)) are currently in class III, however, currently respondents submit 510(k) premarket notifications for these preamendments devices (see proposed order for additional background). The Agency issued a proposed order in the Federal Register of March 25, 2013, "Effective Date of Requirement for Premarket Approval for Automated External Defibrillator System" ([78 FR 17890](#)), which calls for premarket approval applications (PMAs) for AED devices. As a result, respondents will be required to submit PMAs instead of 510(k)s for AEDs. We estimate that we will receive approximately 12 new PMAs for AED devices and 21.5 for AED accessories as a result of the order, causing an increase of approximately 22,378 hours in the PMA ICR (0910-0231).