Premarket Notification (510(k)) (0910-0120)

Change Request 83C

November 4, 2013

FDA is submitting this nonmaterial/nonsubstantive change request (83c) in order to reduce the burden estimate for OMB control number 0910-0120, Premarket Notification (510(k)), by 4 responses and 182 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 reclassification of medical devices under section 515(i) of the Federal Food, Drug, and Cosmetic Act.

Specifically, the burden change is a result of the reclassification of (1) intra-aortic balloon and control system devices (IABPs) when indicated for acute coronary syndrome, cardiac and non-cardiac surgery, or complications of heart failure; and (2) external counter-pulsating devices (ECPs) for treatment of chronic stable angina that is refractory to optimal anti-anginal medical therapy and without options for revascularization. Both are currently class III devices for which manufacturers must submit premarket notifications (510(k)s). The proposed orders below propose to reclassify the devices into class II. Respondents will continue to submit 510(k) premarket notifications for the device for this use and, as noted in the proposed orders, we estimate that we will receive additional 510(k)s as a result of the reclassification.

The Agency issued proposed orders for the reclassification of these devices as listed below:

Device	Proposed Order	Hourly Burden Decrease
IABP	"Cardiovascular Devices; Reclassification of Intra-Aortic Balloon and Control Systems (IABP) for Acute Coronary Syndrome, Cardiac and Non-Cardiac Surgery, or Complications of Heart Failure; Effective Date of Requirement for Premarket Approval for IABP for Other Specific Intended Uses" (78 FR 36702, June 19, 2013)	91
ECP	"Cardiovascular Devices; Reclassification of External Counter-Pulsating Devices for Treatment of Chronic Stable Angina; Effective Date of Requirement for Premarket Approval for External Counter-Pulsating Devices for Other Specified Intended Uses" (78 FR 29672, May 21, 2013)	91