

Premarket Approval of Medical Devices (0910-0231)

Change Request 83C

August 29, 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 7 responses and 2,421 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.

Total Metal-on-Metal (MoM) Semi-constrained Hip Joint Systems (“MoM hips”), include the following two specific preamendments devices: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. These devices 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 January 18, 2013, “Effective Date of Requirement for Premarket Approval for Two Class III Preamendments Devices” ([78 FR 4094](#)), which calls for premarket approval applications (PMAs) for MoM hip 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 7 new PMAs for MoM hip devices as a result of the order, causing an increase of approximately 2,421 hours in the PMA ICR (0910-0231).