

Premarket Approval of Medical Devices (0910-0231)

Change Request 83C

February 11, 2015

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 3 responses and 1,038 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.

Nonroller-Type Cardiopulmonary Bypass Blood Pump (NRP) devices for temporary ventricular support 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 7, 2014, "Cardiovascular Devices; Reclassification of Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass; Effective Date of Requirement for Premarket Approval for Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Temporary Ventricular Support" ([79 FR 765](#)), which calls for premarket approval applications (PMAs) for NRP devices used for ventricular support. As a result, respondents will be required to submit PMAs instead of 510(k)s for these devices. We estimate that we will receive approximately 3 new PMAs for these devices as a result of the order, causing an increase of approximately 1,038 hours in the PMA ICR (0910-0231).