Premarket Approval of Medical Devices (0910-0231)

Change Request 83C

November 4, 2013

FDA is submitting this nonmaterial/nonsubstantive change request (83c) in order to add 2 responses and 692 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 call for premarket approval applications (PMAs) for sorbent hemoperfusion devices for the treatment of hepatic coma and metabolic disturbances. The Agency issued a proposed order, "Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Devices; Reclassification of Sorbent Hemoperfusion Devices for the Treatment of Poisoning and Drug Overdose" (78 FR 20268, April 4, 2013) regarding the proposed call for premarket approval applications (PMAs). The portion of burden shift requested for sorbent hemoperfusion devices for the treatment of hepatic coma and metabolic disturbances is noted above. There are currently no actively marketed products that are cleared for the indication of hepatic coma and metabolic disturbances. However, FDA projects that two firms are likely to enter the market in the near future. Because there are currently no 510(k)s associated with sorbent hemoperfusion devices for this use, we have not submitted a corresponding change request for the Premarket Notification (510(k)) ICR for this device.

The April 4, 2013, proposed order included the reclassification of three devices (sorbent hemoperfusion devices for the treatment of hepatic coma and metabolic disturbances, and for the treatment of poisoning and drug overdose; transilluminator for breast evaluation; and cranial electrotherapy stimulator (CES) for the treatment of depression, anxiety, and insomnia). Because the Agency is not finalizing the call for PMAs for CES devices at this time, we are not including the portion of the estimated burden shift associated with CES devices in this change request.

The transilluminator for breast evaluation is currently a class III device for which manufacturers must submit premarket notifications (510(k)s). The April 4, 2013, proposed order proposes to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the transilluminator. However, there are currently no 510(k)s associated with the device and we do not expect to receive any new PMAs for this device. Therefore, we estimate that there is no burden shift associated with the transilluminator for breast evaluation.

Additionally, no burden shift is associated with the reclassification of sorbent hemoperfusion devices for the treatment of poisoning and drug overdose. This is currently a class III device for which manufacturers must submit premarket notifications (510(k)s). The April 4, 2013, proposed order proposes to reclassify sorbent hemoperfusion devices for the treatment of poisoning and drug overdose into class II, therefore respondents will continue to submit 510(k) premarket notifications for the device for this use.