"Premarket Notification Submission 510(k), Subpart E"
(OMB Control Number 0910-0120)

Change Request (83-C)

December 12, 2012

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) for approval of a change from optional to required electronic submission of an electronic copy of the product approval submissions covered in the following ICRs: 0910-0120 (510(k)), 0910-0078 (IDE), 0910-0231 (PMA), 0910-0705 (513(g)), 0910-0332 and 0910-0661 (HDE), and 0910-0595 (EUA).

Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (See Public Law No: 112-144).

FDA's implementing guidance (attached) describes how device companies should replace one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy requirement does not require or request any information that is not already submitted to the Agency and/or covered under an existing ICR. The process is literally as simple as saving the submission to CD rather than printing an additional copy. Because we have determined that there is no change in the hour burden between an all-paper submission and one with an eCopy and there is no change to the cost burden (the validation software is free, and optional), FDA does not believe the new eCopy requirement will change any cost or hourly burden in any of the existing ICRs.