"Reclassification Petitions for Medical Devices"
(OMB Control Number 0910-0138)

Change Request (83-C)

July 24, 2012

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) in order to slightly modify a form associated with OMB control number 0910-0138.

FDA received a citizen petition prompting the agency to re-evaluate the information presented in FDA Form 3429 (FDA-2012-P-0493-0001/CCP). After careful consideration, FDA has determined that unnecessary information has been included in FDA Form 3429 and that the extraneous information has proven confusing to readers. The extraneous information in the last column and in row 4 describes merely one approach of understanding device classifications, albeit not the only approach, and has caused considerable confusion among FDA and stakeholders while providing little to no benefit. The information is being removed simply for clarity and does not bear on the underlying program or on the hour or cost burden associated with the collection of information. For consistency, we made minor conforming changes in the instructions on page 3.