1410.405

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

NOTIFICATION TO PETITIONERS OF DETERMINATIONS MADE ON PETITIONS FOR RECLASSIFICATION OF MEDICAL DEVICES

Effective Date: July 3, 2014

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c(f) and 360 j(1)) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the Act (21 U.S.C. 360c(e)) (except for petitions submitted in response to Federal Register notices initiating standard-setting under section 514(b) of the Act (21 U.S.C. 360d(b)) or premarket approval under section 515(b) of the Act (21 U.S.C. 360e(b)):

1. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), Office of Medical Products and Tobacco (OMPT).

2. Director and Deputy Directors, Office of Device Evaluation, CDRH, OMPT.

3. Director and Deputy Director, Office of In Vitro Diagnostics and Radiological Health, CDRH, OMPT.

4. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT.

5. Director and Deputy Directors, Office of Blood Research and Review, CBER, OMPT.

6. Director and Deputy Director, Office of Vaccines Research and Review, CBER, OMPT.

7. Director and Deputy Director, Office of Cellular, Tissue and Gene Therapies, CBER, OMPT.

8. Director and Deputy Directors, Center for Drug Evaluation and Research, (CDER), OMPT.

9. Director and Deputy Director, Office of New Drugs, CDER, OMPT.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on July 3, 2014.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OO/ OM/OMP	Commissioner of Food and Drugs
Revision	02/24/2011	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	07/03/2014	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs