

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

REQUESTS FOR INFORMATION CONCERNING DEVICE CLASSIFICATION (IF ANY) AND REQUIREMENTS

Effective Date: December 2, 2013

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to provide, in response to a written request pursuant to Section 513(g) of the Federal Food, Drug and Cosmetic Act (the Act), a written statement of the classification (if any) of a device and the requirements of the act applicable to the device:

1. Center for Devices and Radiological Health (CDRH), Office of Medical Products and Tobacco (OMPT):
 - a. Director and Deputy Directors, CDRH, OMPT.
 - b. Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, OMPT.
 - c. Director Program Operations Staff, ODE, CDRH, OMPT.
 - d. Director 510(k) Staff, ODE, CDRH, OMPT.
 - e. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health, CDRH, OMPT.
2. Center for Biologics Evaluation and Research:
 - a. Director and Deputy Director, CBER, OMPT.
 - b. Director and Deputy Director, Office of Blood Research and Review, CBER, OMPT.
 - c. Director and Deputy Director, Office of Vaccines Research and Review, CBER, OMPT.
 - d. Director and Deputy Director, Office of Cellular, Tissue and Gene Therapies, CBER, OMPT.

2. REDELEGATION.

These officials may not further redelegate these authorities. Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her "acting" or unless not legally permissible.

3. EFFECTIVE DATE.

The Deputy Commissioner for Operations & Chief Operating Officer approved this delegation, via memorandum on December 2, 2013.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/22/2012	N/a	CDRH/OMO	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	12/02/2013	N/a	CDRH/OMO/ DEMO/AMB	Walter S. Harris, M.B.A., Deputy Commissioner for Operations & Chief Operating Officer