

SMG 1410.417

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - MEDICAL DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICE TRACKING

Effective Date: November 22, 2013

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following Officials are authorized to issue orders under Section 519(e) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360i(e)) requiring manufacturers to adopt methods of tracking devices:

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 Compliance, CDRH, OMPT.
3. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health, CDRH, OMPT.
4. Director and Deputy Directors, Office of Device Evaluation, CDRH, OMPT.

2. REDELEGATION.

These Officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Deputy Commissioner for Operations & Chief Operating Officer approved this delegation, via memorandum, on November 22, 2013.

| 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 | 11/22/2013 | N/a | CDRH/OMO/ DEMO/AMB | Walter S. Harris, M.B.A. Deputy Commissioner for Operations & Chief Operating Officer |