**SMG 1410.409**

# FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

## REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH

## DETERMINATIONS CONCERNING THE TYPE OF VALID SCIENTIFIC EVIDENCE SUBMITTED IN A PREMARKET APPROVAL APPLICATION

Effective Date: November 13, 2018

## 1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The officials listed below, for medical devices assigned to their respective organization, are authorized to make determinations under Section 513(a)(3)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c(a)(3)(D)) concerning the type of valid scientific evidence to be submitted in a premarket approval application that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person:

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

2. Director, Deputy Directors, and Associate Directors, Office of Compliance (OC), CDRH, OMPT.

3. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.

4. Director, Deputy Directors, and Associate Directors, Office of Device Evaluation (ODE), CDRH, OMPT.

5. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.

6. Director, Program Operations Staff (POS), ODE, CDRH, OMPT.

7. Director, Deputy Directors, and Associate Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.

8. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.

9. Director, Deputy Directors, and Associate Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.

10. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

## 2. REDELEGATION.

These officials may not further redelegate this authority.

## 3. EFFECTIVE DATE.

These delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this Delegation, via memorandum, on November 13, 2018.

| STATUS | 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 | 04/01/2011 | N/a | CDRH/OMO/ DEMO/AMB | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 07/14/2014 | N/a | CDRH/OMO/ DEMO/AMB | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 11/13/2018 | N/a | OMPT/CDRH/ OM/DWM | Scott Gottlieb, M.D. Commissioner of Food and Drug |

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