

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

**REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH**

**DETERMINATION OF CLASSIFICATION OF DEVICES**

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 determine the classification of a medical device in commercial distribution prior to May 28, 1976, under Section 513(d) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c(d)):

1. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco (OMPT).
2. Director and Deputy Directors, Office of Blood Research and Review (OBRR), CBER, OMPT.
3. Director and Deputy Director, Office of Tissues and Advanced Therapies (OTAT), CBER, OMPT.
4. Director and Deputy Director, Office of Vaccines Research and Review (OVRR), CBER, OMPT.
5. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), OMPT.
6. Director and Deputy Director, Office of New Drugs (OND), CDER, OMPT.
7. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT.
8. Director, Deputy Directors, and Associate Directors, Office of Compliance (OC), CDRH, OMPT.
9. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.
10. Director, Deputy Directors, and Associate Directors, Office of Device Evaluation (ODE), CDRH, OMPT.

11. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.
  12. Director, Deputy Directors, and Associate Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.
  13. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.
  14. Director, Deputy Directors, and Associate Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.
  15. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.
- B. The officials listed below, for medical devices assigned to their respective organization, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, under Section 513 (f)(1)(A) of the Act (21 U.S.C. 360c(f)(1)(A)):
1. Director and Deputy Director, CBER, OMPT.
  2. Director and Deputy Directors, OBRR, CBER, OMPT.
  3. Director and Deputy Director, OTAT, CBER, OMPT.
  4. Director and Deputy Director, OVRP, CBER, OMPT.
  5. Director and Deputy Directors, CDRH, OMPT.
  6. Director, Deputy Directors, and Associate Directors, OC, CDRH, OMPT.
  7. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, OC, CDRH, OMPT.
  8. Director, Deputy Directors, and Associate Directors, ODE, CDRH, OMPT.
  9. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, ODE, CDRH, OMPT.
  10. Director, Program Operations Staff (POS), ODE, CDRH, OMPT.
  11. Chief, Premarket Notification Section (510(K)), POS, ODE, CDRH, OMPT.
  12. Director, Deputy Directors, and Associate Directors, OIR, CDRH, OMPT.

13. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, OIR, CDRH, OMPT.
14. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.
15. Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs, OSB, CDRH, OMPT.

C. The officials listed below, for medical devices assigned to their respective organization, are authorized to make determinations and issue orders classifying devices under Section 513(f)(2)(B) of the Act (21 U.S.C. (f)(2)(B)):

1. Director and Deputy Director, CBER, OMPT.
2. Director and Deputy Directors, OBRR, CBER, OMPT.
3. Director and Deputy Director, OTAT, CBER, OMPT.
4. Director and Deputy Director, OVRR, CBER, OMPT.
5. Director and Deputy Directors, CDRH, OMPT.
6. Director, Deputy Directors, and Associate Directors, OC, CDRH, OMPT.
7. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.
8. Director, Deputy Directors, and Associate Directors, ODE, CDRH, OMPT.
9. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.
10. Director, Deputy Directors, and Associate Directors, OIR, CDRH, OMPT.
11. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.
12. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.
13. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

D. The officials listed below, for medical devices assigned to their respective organization, are authorized to issue Federal Register notices under Section 513(f)(2)(C) of the Act (21 U.S.C. 360c(f)(2)(C)) announcing classification of devices under Section 513(f)(2)(B) of the Act (21 U.S.C. 360c(f)(2)(B)):

1. Director and Deputy Director, CBER, OMPT.
  2. Director and Deputy Directors, OBRR, CBER, OMPT.
  3. Director and Deputy Director, OTAT, CBER, OMPT.
  4. Director and Deputy Director, OVR, CBER, OMPT.
  5. Director and Deputy Director, CDRH, OMPT.
- E. The officials listed below, for medical devices assigned to their respective organization, are authorized to make determinations and issue orders for accessory device classification requests under Section 513(f)(6) of the Act (21 U.S.C. 360c(f)(6)):
1. Director and Deputy Directors, CDRH, OMPT.
  2. Director, Deputy Directors, and Associate Directors, OC, CDRH, OMPT.
  3. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.
  4. Director, Deputy Directors, and Associate Directors, ODE, CDRH, OMPT.
  5. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.
  6. Director, Deputy Directors, and Associate Directors, OIR, CDRH, OMPT.
  7. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.
  8. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.
  9. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

## **2. REDELEGATION.**

These officials may not further redelegate these authorities.

### 3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

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

<b>STATUS</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	06/23/2009	N/a	OC/OO/OM/OMP	Commissioner of Food and Drugs
Revision	01/24/2011	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
Revision	06/23/2015	N/a	CDRH/OMO/DEMO/AMB	Stephen M. Ostroff, M.D. Acting Commissioner of Food and Drugs
Revision	11/13/2018	N/a	OMPT/CDRH/OM/DWM	Scott Gottlieb, M.D. Commissioner of Food and Drugs

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