

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Determination of Classification of Medical Devices

Effective Date: 14 May 2024

1. Authority Delegated and to Whom Delegated.

- A. The officials listed below, for medical devices assigned to their respective organization, are authorized under section 513(d) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c(d)) to determine the classification of a medical device in commercial distribution prior to May 28, 1976:
- (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.
 - (2) CBER/Office of Blood Research and Review (OBRR) Director and Deputy Director.
 - (3) CBER/Office of Therapeutic Products (OTP) Director and Deputy Director.
 - (4) CBER/Office of Vaccines Research and Review (OVR) Director and Deputy Director.
 - (5) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.
 - (6) CDER/Office of New Drugs (OND) Director and Deputy Director.
 - (7) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
 - (8) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.
 - (9) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical and Science Officer.
 - (10) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.
 - (11) CDRH/OPEQ/Office of Health Technology I (OHT I) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (12) CDRH/OPEQ/Office of Health Technology II (OHT II) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.

- (13) CDRH/OPEQ/Office of Health Technology III (OHT III) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (14) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (15) CDRH/OPEQ/Office of Health Technology V (OHT V) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (16) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (17) CDRH/OPEQ/Office of Health Technology VII (OHT VII) Director, Deputy Directors, Associate Director for Strategic Initiatives, Chief Medical Officers, Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs.
- (18) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (19) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director, Deputy Directors, and Chief Medical Officer.
- (20) CDRH/OPEQ/ORP/Division of Regulatory Programs 1 (DRP1) Director and Deputy Director.

B. The officials listed below, for medical devices assigned to their respective organization, are authorized under section 513 (f)(1)(A) of the Act (21 U.S.C. 360c(f)(1)(A)) to determine the classification of a medical device first intended for commercial distribution after May 28, 1976:

- (1) CBER Director and Deputy Director.
- (2) CBER/OBRR Director and Deputy Director.
- (3) CBER/OBRR/Division of Blood Components and Devices (DBCD) Director and Deputy Director.
- (4) CBER/OBRR/Division of Emerging and Transfusion Transmitted Diseases (DETTD) Director and Deputy Director.
- (5) CBER/OTP Director, Deputy Director, and Associate Director for Regulatory Management.
- (6) CBER/OTP/Office of Cellular Therapy and Human Tissue CMC (OCTHTCMC) Director and Deputy Director.
- (7) CBER/OTP/Office of Clinical Evaluation (OCE) Director and Deputy Director.

- (8) CBER/OTP/Office of Gene Therapies CMC (OCTCMC) Director and Deputy Director.
 - (9) CBER/OTP/Office of Pharmacology and Toxicology (OPT) Director and Deputy Director.
 - (10) CBER/OTP/Office of Plasma Protein Therapeutics CMC (OPPTCMC) Director and Deputy Director.
 - (11) CBER/OTP/Office of Review Management and Regulatory Review (ORMRR) Director and Deputy Director.
 - (12) CBER/OVRR Director and Deputy Director.
 - (13) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
 - (14) CDRH/OPEQ Director and Deputy Directors.
 - (15) CDRH/OPEQ/CSPS Chief Medical and Science Officer.
 - (16) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.
 - (17) CDRH/OPEQ/OHT I Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (18) CDRH/OPEQ/OHT II Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (19) CDRH/OPEQ/OHT III Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (20) CDRH/OPEQ/OHT IV Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (21) CDRH/OPEQ/OHT V Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (22) CDRH/OPEQ/OHT VI Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (23) CDRH/OPEQ/OHT VII Director, Deputy Directors, Associate Director for Strategic Initiatives, Chief Medical Officers, Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs.
 - (24) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (25) CDRH/OPEQ/ORP Director, Deputy Directors, and Chief Medical Officer.
 - (26) CDRH/OPEQ/ORP/DRP1 Director and Deputy Director.
- C. The officials listed below, for medical devices assigned to their respective organization, are authorized under section 513(f)(2)(B) of the Act (21 U.S.C. (f)(2)(B)) to make determinations and issue orders classifying devices:
- (1) CBER Director and Deputy Director
 - (2) CBER/OBRR Director and Deputy Director.

- (3) CBER/OTP Director, Deputy Director, and Associate Director for Regulatory Management.
 - (4) CBER/OVRR Director and Deputy Director.
 - (5) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
 - (6) CDRH/OPEQ Director and Deputy Directors.
 - (7) CDRH/OPEQ/CSPS Chief Medical and Science Officer.
 - (8) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.
 - (9) CDRH/OPEQ/OHT I Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (10) CDRH/OPEQ/OHT II Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (11) CDRH/OPEQ/OHT III Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (12) CDRH/OPEQ/OHT IV Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (13) CDRH/OPEQ/OHT V Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (14) CDRH/OPEQ/OHT VI Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (15) CDRH/OPEQ/OHT VII Director, Deputy Directors, Associate Director for Strategic Initiatives, Chief Medical Officers, Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs.
 - (16) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
 - (17) CDRH/OPEQ/ORP Director, Deputy Directors, and Chief Medical Officer.
 - (18) CDRH/OPEQ/ORP/DRP1 Director and Deputy Director.
- D. The officials listed below, for medical devices assigned to their respective organization, are authorized under section 513(f)(2)(C) of the Act (21 U.S.C. 360c(f)(2)(C)) to issue Federal Register notices announcing classification of devices under section 513(f)(2)(B) of the Act (21 U.S.C. 360c(f)(2)(B)):
- (1) CBER Director and Deputy Director.
 - (2) CBER/OBRR Director and Deputy Director.
 - (3) CBER/OTP Director and Deputy Director.
 - (4) CBER/OVRR Director and Deputy Director.
 - (5) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

E. The officials listed below, for medical devices assigned to their respective organization, are authorized under section 513(f)(6) of the Act (21 U.S.C. 360c(f)(6)) to make determinations and issue orders for accessory device classification requests:

- (1) CBER Director and Deputy Director.
- (2) CBER/OBRR Director and Deputy Director.
- (3) CBER/OTP Director, Deputy Director, and Associate Director for Regulatory Management.
- (4) CBER/OVRR Director and Deputy Director.
- (5) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (6) CDRH/OPEQ Director and Deputy Directors.
- (7) CDRH/OPEQ/CSPS Chief Medical and Science Officer.
- (8) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.
- (9) CDRH/OPEQ/OHT I Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (10) CDRH/OPEQ/OHT II Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (11) CDRH/OPEQ/OHT III Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (12) CDRH/OPEQ/OHT IV Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (13) CDRH/OPEQ/OHT V Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (14) CDRH/OPEQ/OHT VI Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (15) CDRH/OPEQ/OHT VII Director, Deputy Directors, Associate Director for Strategic Initiatives, Chief Medical Officers, Division Directors, Deputy Division Directors, Associate Division Directors, and Branch Chiefs.
- (16) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (17) CDRH/OPEQ/ORP Director, Deputy Directors, and Chief Medical Officer.
- (18) CDRH/OPEQ/ORP/DRP1 Director and Deputy Director.

2. Redlegation.

These officials may not further redelegate these authorities.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 14 May 2024.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/23/2009	N/A	OC/ OA/ OM/OMP	Margret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	02/24/2011	N/A	CDRH/ OMO/ DEMO	Margret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	07/03/2014	N/A	OMPT/ CDRH/ OMO/ DEMO	Margret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	06/23/2015	N/A	OMPT/ CDRH/ OMO/ DEMO	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
Revision	05/14/2024	N/A	CDRH/ OM/ DWM	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs