SMG 1410.420

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Requests for Information Concerning Device Classification and Requirements

Effective Date: 23 May 2024

1. Authority Delegated and To Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to provide in response to a written request pursuant to section 513(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(g)) (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 Biologics Evaluation and Research (CBER) Director and Deputy Directors.

(2) CBER/Office of Blood Research and Review (OBRR) Director and Deputy Directors.

(3) CBER/Office of Compliance and Biologics Quality (OCBQ) Director and Deputy Director.

(4) CBER/Office of Therapeutic Products (OTP) Director and Deputy Director.

(5) CBER/OTP/Office of Cellular Therapy and Human Tissue (OCTHT) Director and Deputy Director.

(6) CBER/Office of Vaccines Research and Review (OVRR) Director and Deputy Director.

(7) Center for Devices and Radiological Health (CDRH) Director, and Deputy Center Directors.

(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 Clinical Evidence and Analysis (OCEA) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(12) CDRH/OPEQ/OCEA/Division of Clinical Evidence and Analysis 1 (DCEA1) Director, Deputy Director, and Assistant Director.

(13) CDRH/OPEQ/Office of Health Technology I (OHT I) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(14) CDRH/OPEQ/Office of Health Technology II (OHT II) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(15) CDRH/OPEQ/Office of Health Technology III (OHT III) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(16) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(17) CDRH/OPEQ/Office of Health Technology V (OHT V) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(18) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(19) CDRH/OPEQ/Office of Health Technology VII (OHT VII) Director, Deputy Directors, Associate Director for Strategic Initiatives, and Chief Medical Officers.

(20) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(21) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(22) CDRH/OPEQ/ORP/Division of Regulatory Programs 1 (DRP1) Director, Deputy Director, and Assistant Director.

2. Redelegation.

These officials may not redelegate this authority.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 23 May 2024.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/06/2008	N/A	OC/ OA/ OM/OMP	Andrew C. von Eschenbach, M.D. Commissioner of Food and Drugs
Revision	06/22/2012	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	12/02/2013	N/A	OMPT/ CDRH/ OMO/ DEMO	Walter S. Harris, MBA Deputy Commissioner for Operations & Chief Operating Officer

Status	Date Approved	Location of Change History	Contact	Approving Official
Revision	05/23/2024	N/A	CDRH/ OM/ DWM	Robert M. Califf, M.D., MACC Commissioner of Food and Drugs