SMG 1410.418

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Accreditations for Medical Devices

Effective Date: 4 March 2022

1. Authority Delegated and to Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized under sections 523(a)(1) and (b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360m(a)(1) and (b)(2)(A)) to respond to a request for accreditation and to accredit persons for reviewing reports submitted under section 510(k) of the Act (21 U.S.C. 360(k)) and making recommendations regarding the initial classification of devices:

(1) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(2) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.

(3) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical & Science Officer.

(4) CDRH/OPEQ/Compliance and Quality Staff (CQS) Associate Director for Compliance and Quality.

(5) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.

B. The officials listed below, for medical devices assigned to their respective organizations, are authorized under sections 523(a)(2)(B) and (C) of the Act (21 U.S.C. 360m(a)(2)(B) and (C)) to make a determination with respect to the recommendation of an initial classification of a device; and to change the initial classification under section 513(f)(1) of the Act (21 U.S.C. 360c(f)(1)) that is recommended by an accredited person to provide to such person, and the person who submitted the report under section 510(k) of the Act (21 U.S.C. 360(k)) for the device, a statement explaining the reasons for the change:

(1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(2) CDRH/OPEQ Director and Deputy Directors.

(3) CDRH/OPEQ/CSPS Chief Medical & Science Officer.

(4) CDRH/OPEQ/CQS Associate Director for Compliance and Quality.

(5) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy

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

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

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

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

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

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

(12) 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, and Associate Division Directors.

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

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

C. The officials listed below, for medical devices assigned to their respective organizations, are authorized under section 523(b)(2)(B) of the Act (21 U.S.C. 360m(b)(2)(B)) to suspend or withdraw accreditation of any person accredited to review reports and to make recommendations under section 523 of the Act (21 U.S.C. 360m):

(1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(2) CDRH/OPEQ Director and Deputy Directors.

(3) CDRH/OPEQ/CSPS Chief Medical and Science Officer.

(4) CDRH/OPEQ/CQS Associate Director for Compliance and Quality.

(5) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.

D. The officials listed below, for medical devices assigned to their respective organizations, are authorized under section 523(b)(2)(C) of the Act (21 U.S.C. 360m(b)(2)(C)) to implement the measures described in that section to ensure that persons accredited under section 523 of the Act (21 U.S.C. 360m) will continue to meet the standards of accreditation:

(1) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(2) CDRH/OPEQ Director and Deputy Directors.

(3) CDRH/OPEQ/CSPS Chief Medical & Science Officer.

(4) CDRH/OPEQ/CQS Associate Director for Compliance and Quality.

(5) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.

2. Redelegation.

These officials may not further redelegate these authorities.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 4 March 2022.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/23/2009	N/A	OC/ OA/ OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	03/29/2012	N/A	CDRH/ OMO/ DEMO	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	11/22/2013	N/A	OMPT/ CDRH/ OMO/ DEMO	Walter S. Harris, MBA Deputy Commissioner for Operations & Chief Operating Officer
Revision	10/29/2018	N/A	OMPT/ CDRH/ OMO/ DEMO	Scott Gottlieb, M.D. Commissioner of Food and Drugs
Revision	03/04/2022	N/A	CDRH/ OM/ DWM	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs