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: 24 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 section 513(a)(3)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(3)(D)) to make determinations 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) 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 and 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.

(6) CDRH/OPEQ/Office of Clinical Evidence and Analysis (OCEA) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

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

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

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

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

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

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

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

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

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

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

2. Redelegation.

These officials may not further redelegate this authority.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 24 March 2022.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/23/2009	N/A	OC/ OA/ OM/OMP	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	04/01/2011	N/A	CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	07/14/2014	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	11/13/2018	N/A	OMPT/ CDRH/ OMO/ DWM	Scott Gottlieb, M.D. Commissioner of Food and Drugs
Revision	03/24/2022	N/A	CDRH/ OMO/ DWM	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs