SMG 1410.404

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Use of Alternative Evidence for Determination of the Effectiveness of Medical Devices

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, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c(a)(3)(B)) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the Act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the Act (21 U.S.C. 360c, 360d, and 360e):

(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/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/Office of Therapeutic Products (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/Office of Vaccines Research and Review (OVRR) Director and Deputy Director.

(13) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.

(14) CDER/Office of New Drugs (OND) Director and Deputy Directors.

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

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

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

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

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

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

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

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

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

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

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

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

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

(28) CDRH/OPEQ/ORP/Division of Regulatory Programs 1 (DRP1) Division Director, Deputy Division Directors, and Assistant Division Director for Premarket Approval, Humanitarian Device Exemption, Presubmission, and Device Tracking Lifecycle.

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 23 May 2024.

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	02/17/2011	N/A	CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	07/03/2014	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	05/23/2024	N/A	CDRH/ OM/ DWM	Robert M. Califf, M.D., MACC Commissioner of Food and Drugs