SMG 1410.417

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Medical Device Tracking

Effective Date: 23 May 2024

1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to issue orders requiring manufacturers to adopt methods of tracking devices under section 519(e) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360i(e)):

(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 Health Technology I (OHT I) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

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

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

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

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

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

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

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

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

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	11/22/2013	N/A	OMPT/ CDRH/ OMO	Walter S. Harris, MBA Deputy Commissioner for Operations & Chief Operating Officer
Revision	06/02/2021	N/A	CDRH/ OM/ DWM	Janet Woodcock, M.D. Acting 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