SMG 1258.63

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Devices and Radiological Health

Office of Product Evaluation and Quality

Office of Health Technology IV

Division of Health Technology IV C

Effective: January 22, 2024

1. Division of Clinical Evidence and Analysis IV C (DCCFFC).

A. Serves as the primary source for scientific and medical expertise on medical devices with regard to safety and effectiveness.

B. Carries out scientific and end-to-end medical device review evaluation.

C. Coordinates actions on classification of medical devices.

D. Coordinates, carries out, and makes premarket review determinations.

E. Plans and coordinates post market compliance and enforcement efforts related to medical devices. Participates in development and interpretation of post market regulations and policies related to medical devices.

F. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.

2. Authority and Effective Date.

The functional statements for the Division Clinical Evidence and Analysis IV C were approved by the Secretary of Health and Human Services on December 21, 2023, and effective on January 22, 2024.

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Product Evaluation and Quality
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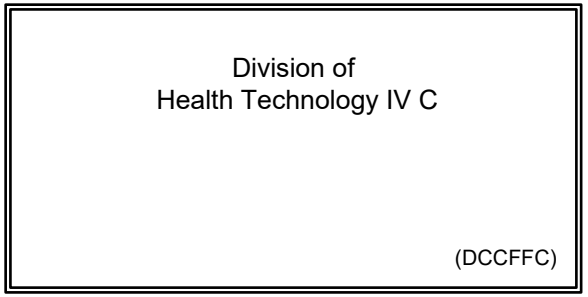

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Product Evaluation and Quality, Office of Health Technology IV, Division of Health Technology IVC organization structure depicting all the organizational structures reporting to the Director:

Division of Health Technology IV C (DCCFFC)