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 Clinical Evidence and Analysis

Division of Clinical Evidence and Analysis III

Effective Date: February 9, 2022

1. Division of Clinical Evidence and Analysis III (DCCFBC).

- A. Collaboratively supports Center in assuring the enforcement of the Medical Device Amendments of 1976 including the Safe Medical Devices Act of 1990 and 1992, the Food and Drug Administration Modernization Act and the Radiation Control for Health and Safety Act of 1972 relating to the safety and effectiveness of medical devices and radiation-emitting electronic products.
- B. Responsible for developing policy and providing program support across clinical evidence areas, including clinical evidence synthesis, analysis, and infrastructure development, for Device Specific Offices engaged in total product lifecycle review of devices.
- C. Responsible for conducting outreach and collaboration with hospitals and other external stakeholders.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Evidence and Analysis III were approved by the Secretary of Health and Human Services and effective on February 9, 2022.

Staff Manual Guide 1258.23 Organizations and Functions Effective Date: February 9, 2022

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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 Clinical Evidence and Analysis, Division of Clinical Evidence & Analysis III organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Evidence & Analysis III (DCCFBC)