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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 I

Effective Date: February 9, 2022

1. Division of Clinical Evidence and Analysis I (DCCFBA).

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 investigations, bioresearch compliance, and human subject protection for Device Specific Offices engaged in total product lifecycle review of devices.

C. Responsible for postmarket clinical evidence generation in support of Device Specific Offices.

2. Authority and Effective Date.

The functional statements for the Division of Clinical Evidence and Analysis I were approved by the Secretary of Health and Human Services and effective on 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 I organization structure depicting all the organizational structures reporting to the Director.

Division of Clinical Evidence & Analysis I (DCCFBA)