

SMG 1257.2

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH

DIVISION OF CHEMISTRY AND TOXICOLOGY DEVICES

Effective Date: 09/25/2012

1. DIVISION OF CHEMISTRY AND TOXICOLOGY DEVICES (DKKWJA).

- A. Serves as the primary source for scientific and medical expertise on clinical chemistry and toxicology devices with regard to safety and effectiveness.
- B. Carries out scientific and medical review evaluation for documents related to classification, petitions, 510(k)s, Humanitarian Device Exemptions (HDEs), premarket approval applications (PMAs), product development protocols (PDPs), investigational device exemptions (IDEs), and all supplements and amendments to these submissions, as authorized.
- C. Makes preliminary determinations of equivalence or nonequivalence and of approval or nonapproval for actions related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions, as authorized.
- D. Provides technical and nontechnical support to device advisory panels and panel members and consultants.
- E. Coordinates actions on classification actions, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs with Center and Agency components or other organizations, when appropriate.
- F. Enforces the Medical Device Amendments of 1976 and subsequent medical device laws and regulations relating to clinical chemistry and toxicology in vitro diagnostic devices.
- G. Manages and coordinates activities associated with administrative and

regulatory actions.

- H. In accordance with the Clinical Laboratory Improvement Amendments (CLIA), performs CLIA complexity categorization functions.
- I. Develops and interprets policy guidance in response to specific requests from the medical device industries, trade associations, other Federal agencies, other countries, State agencies, and the general public. Develops, reviews, and revises new and amended regulations including good manufacturing practices (GMPs).
- J. Plans, initiates, and coordinates medical device inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.
- K. Identifies the need for and directs the development of Compliance Policy Guides and programs to facilitate compliance by manufacturers. Develops, coordinates, reviews, and revises medical device industry GMP regulations. Develops and implements programs to ensure uniform interpretation and application of GMPs and recommends regulatory action when appropriate.

2. CHEMISTRY BRANCH (DKKWJA1).

- A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic clinical chemistry medical devices.
- B. Coordinates, carries out, and makes preliminary premarket review determinations for clinical chemistry medical devices related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.
- C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to clinical chemistry medical devices.

3. DIABETES BRANCH (DKKWJA2).

- A. Serves as the primary source for regulatory, scientific and medical expertise on in vitro diagnostic devices for the management of diabetes.
- B. Coordinates, carries out, and makes preliminary premarket review determinations for in vitro diagnostic devices for the management of diabetes related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.

- C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to in vitro diagnostic devices for the management of diabetes.

4. TOXICOLOGY BRANCH (DKKWJA3).

- A. Serves as the primary source for regulatory, scientific and medical expertise on clinical toxicology in vitro diagnostic medical devices.
- B. Coordinates, carries out, and makes preliminary premarket review determinations for clinical toxicology in vitro diagnostic medical devices related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.
- C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to clinical toxicology in vitro diagnostic medical devices.

5. CARDIO-RENAL DIAGNOSTICS BRANCH (DKKWJA4).

- A. Serves as the primary source for regulatory, scientific and medical expertise on cardio-renal in vitro diagnostic medical devices.
- B. Coordinates, carries out, and makes preliminary premarket review determinations for cardio-renal in vitro diagnostic medical devices related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.
- C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to cardio-renal in vitro diagnostic medical devices.

6. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs on September 25, 2012.

Staff Manual Guide 1257.2
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OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH
DIVISION OF CHEMISTRY AND TOXICOLOGY DEVICES**

OFFICE OF DIRECTOR

Chemistry Branch
Diabetes Branch
Toxicology Branch
Cardio-Renal Diagnostics Branch

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Division of Chemistry and Toxicology Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Chemistry Branch
- Diabetes Branch
- Toxicology Branch
- Cardio-Renal Diagnostics Branch