

SMG 1253.10

**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 DEVICE EVALUATION

**DIVISION OF ANESTHESIOLOGY, GENERAL HOSPITAL, RESPIRATORY
INFECTION CONTROL, AND DENTAL DEVICES (DAGID)**

Effective Date: 09/26/2012

**1. DIVISION OF ANESTHESIOLOGY, GENERAL HOSPITAL, RESPIRATORY
INFECTION CONTROL, AND DENTAL DEVICES (DKKWCF).**

- A. Serves as the primary source for scientific and medical expertise on anesthesia and respiratory, general hospital, infection control, and dental devices with regard to safety and effectiveness.
- B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, 510(k)s, PMAs, PDPs, IDEs, and supplements or amendments to these submissions.
- C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k)s, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions as authorized.
- D. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels, panel members and consultants, and takes action on panel recommendations.
- E. Provides liaison services, coordinates, and takes action as appropriate, on classification, actions, petitions, 510(k)s, PMAs, PDPs, IDEs with Center and Agency components; Federal, State, and International Agencies; and industry, consumer, and professional organizations.

2. GENERAL HOSPITAL DEVICES BRANCH (DKKWCF1).

- A. Serves as the primary source for scientific and medical expertise on general hospital devices with regard to safety and effectiveness.
- B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and supplements or amendments to these submissions.
- C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions as authorized.
- D. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels, panel members and consultants, and takes action on panel recommendations.
- E. Provides liaison services, coordinates, and takes action as appropriate, on classification, actions, petitions, 510(k)s, PMAs, PDPs, IDEs with Center and Agency components; Federal, State, and International Agencies; and industry, consumer, and professional organizations.

3. INFECTION CONTROL DEVICES BRANCH (DKKWCF2).

- A. Serves as the primary source for scientific and medical expertise on infection control devices with regard to safety and effectiveness.
- B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and supplements or amendments to these submissions.
- C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions as authorized.
- D. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels, panel members and consultants, and takes action on panel recommendations.
- E. Provides liaison services, coordinates, and takes action as appropriate, on classification, actions, petitions, 510(k)s, PMAs, PDPs, IDEs with Center

and Agency components; Federal, State, and International Agencies; and industry, consumer, and professional organizations.

4. DENTAL DEVICES BRANCH (DKKWCF3).

- A. Serves as the primary source for scientific and medical expertise on dental devices with regard to safety and effectiveness.
- B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and supplements or amendments to these submissions.
- C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions as authorized.
- D. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels, panel members and consultants, and takes action on panel recommendations.
- E. Provides liaison services, coordinates, and takes action as appropriate, on classification, actions, petitions, 510(k)s, PMAs, PDPs, IDEs with Center and Agency components; Federal, State, and International Agencies; and industry, consumer, and professional organizations.

5. ANESTHESIOLOGY DEVICES BRANCH (DKKWCF4).

- A. Serves as the primary source for scientific and medical expertise on anesthesiology devices with regard to safety and effectiveness.
- B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and supplements or amendments to these submissions.
- C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions as authorized.
- D. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels, panel members and consultants, and takes action on panel recommendations.

- E. Provides liaison services, coordinates, and takes action as appropriate, on classification, actions, petitions, 510(k)s, PMAs, PDPs, IDEs with Center and Agency components; Federal, State, and International Agencies; and industry, consumer, and professional organizations.

6. RESPIRATORY DEVICES BRANCH (DKKWCF5).

- A. Serves as the primary source for scientific and medical expertise on respiratory devices with regard to safety and effectiveness.
- B. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and supplements or amendments to these submissions.
- C. Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k) s, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions as authorized.
- D. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels, panel members and consultants, and takes action on panel recommendations.
- E. Provides liaison services, coordinates, and takes action as appropriate, on classification, actions, petitions, 510(k)s, PMAs, PDPs, IDEs with Center and Agency components; Federal, State, and International Agencies; and industry, consumer, and professional organizations.

7. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health on September 26, 2012.

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STAFF MANUAL GUIDE 1253.10
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 26, 2012

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Device Evaluation, Division of Anesthesiology, General Hospital, Respiratory Infection Control, and Dental Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- General Hospital Devices Branch
- Infection Control Devices Branch
- Dental Devices Branch
- Anesthesiology Devices Branch
- Respiratory Devices Branch