

SMG 1253.9

**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 OPHTHALMIC AND EAR, NOSE, AND THROAT, DEVICES

Effective Date: 09/26/2012

**1. DIVISION OF OPHTHALMIC AND EAR, NOSE AND THROAT DEVICES
(DKKWCE).**

- A. Serves as the primary source for scientific and medical expertise on ophthalmic and ear, nose, and throat 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. INTRAOCULAR AND CORNEAL IMPLANTS DEVICES BRANCH (DKKWCE1).

- A. Participates in the development of National and International consensus standards, and voluntary guidelines through interaction with appropriate National and International standards committees.
- 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.
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3. DIAGNOSTIC AND SURGICAL DEVICES BRANCH (DKKWCE3).

- A. Serves as the primary source for scientific and medical expertise on ophthalmic diagnostic and surgical 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. CONTACT LENSES AND RETINAL DEVICES BRANCH (DKKWCE4).

- A. Serves as the primary source for scientific and medical expertise on contact lenses and retinal 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. EAR, NOSE AND THROAT DEVICES BRANCH (DKKWCE5).

- A. Serves as the primary source for scientific and medical expertise on ear, nose and throat 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. 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 1253.9
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 Ophthalmic, Neurological and Ear, Nose, and Throat Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Contact Lenses and Retinal Devices Branch
- Diagnostic and Surgical Devices Branch
- Intraocular and Corneal Implant Devices Branch
- Ear, Nose and Throat Devices Branch