SMG 1253.12

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 SURGICAL DEVICES

Effective Date: 09/26/2012

1. DIVISION OF SURGICAL DEVICES (DKKWCH).

A. Serves as the primary source for scientific and medical expertise on 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.

2. GENERAL SURGERY DEVICES BRANCH I (DKKWCH1).

A. Serves as the primary source for scientific and medical expertise on surgical, low level and infrared lasers and surgical lamps and camera 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.

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3. GENERAL SURGERY DEVICES BRANCH II (DKKWCH2).

A. Serves as the primary source for scientific and medical expertise on surgical instruments, scopes, cryo, computer assist, biopsy hypo/hyperthermia, and electrosurgical 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. PLASTIC AND RECONSTRUCTIVE SURGERY DEVICES BRANCH I (DKKWCH3).

A. Serves as the primary source for scientific and medical expertise on sutures, hemostatic agents, breast implants, silicone contouring implants, liposuction, surgical meshes and 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.

5. PLASTIC AND RECONSTRICTUVE SURGERY ANESTHESIOLOGY DEVICES BRANCH II (DKKWCH4).

A. Serves as the primary source for scientific and medical expertise on wound dressings, soft tissue fillers, surgical sealants, dermal replacements, wound healing and stimulator 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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FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION
DIVISION OF SURGICAL DEVICES

OFFICE OF THE DIRECTOR

General Surgery Devices Branch I
General Surgery Devices Branch II
Plastic and Reconstructive Surgery Devices Branch I
Plastic and Reconstructive Surgery Devices Branch II

STAFF MANUAL GUIDE 1253.12
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 Surgical Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- General Surgery Devices Branch I
- General Surgery Devices Branch II
- Plastic and Reconstructive Surgery Devices Branch I
- Plastic and Reconstructive Surgery Devices Branch II