SMG 1253.7

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 ORTHOPEDIC DEVICES

Effective Date: 09/26/12

1. DIVISION OF ORTHOPEDIC DEVICES (DKKWCC).

A. Serves as the primary source for scientific and medical expertise on orthopedic 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. RESTORATIVE AND REPAIR DEVICES BRANCH (DKKWCC2).

A. Serves as the primary source for scientific and medical expertise on restorative and repair 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. JOINT AND FIXATION DEVICES BRANCH I (DKKWCC4).

A. Serves as the primary source for scientific and medical expertise on joint prostheses, fracture fixation and orthopedic stereotactic 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. ANTERIOR SPINE DEVICES BRANCH (DKKWCC5).

A. Serves as the primary source for scientific and medical expertise on anterior systems, vertebral body replacements, interbody cages and discs 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. JOINT AND FIXATION DEVICES BRANCH II (DKKWCC6).

A. Serves as the primary source for scientific and medical expertise on joint prostheses, and fracture fixation 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. POSTERIOR SPINE DEVICES BRANCH (DKKWCC7).

A. Serves as the primary source for scientific and medical expertise on posterior/pedicle screws systems, facet spinal systems, pinous process spinal systems 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 Heath 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 ORTHOPEDIC DEVICES

OFFICE OF THE DIRECTOR

Joint and Fixation Devices Branch I
Joint and Fixation Devices Branch II
Restorative and Repair Devices Branch
Anterior Spine Devices Branch
Posterior Spine Devices Branch

STAFF MANUAL GUIDE 1253.7
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 Orthopedic Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Joint and Fixation Devices Branch I
- Joint and Fixation Devices Branch II
- Restorative and Repair Devices Branch
- Anterior Spine Devices Branch
- Posterior Spine Devices Branch