SMG 1253.3

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 CARDIOVASCULAR DEVICES

Effective Date: September 26, 2012

1. DIVISION OF CARDIOVASCULAR DEVICES (DKKWCA).

A. Serves as the primary sources for scientific and medical expertise on cardiovascular 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, premarket notification submissions (510(k) s), premarket approval applications (PMAs), product development protocols (PDPs), investigational device exemptions (IDEs), and supplements or amendments to these submissions.

C. Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to PMA device specific quality and manufacturing information as well as 30 Day Notices and 135 (75) Day supplements.

D. 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.

E. Provides executive secretarial support and other technical and nontechnical support to devices advisory panels and panel members and consultants, and takes action on panel recommendations.

F. 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. CIRCULATORY SUPPORT DEVICES BRANCH (DKKCA1).

A. Serves as the primary sources for scientific and medical expertise on circulatory support 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. CARDIAC DIAGNOSTICS DEVICES BRANCH (DKKWCA2).

A. Serves as the primary sources for scientific and medical expertise on cardiac diagnostic 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. IMPLANTABLE ELECTROPHYSIOLOGY DEVICES BRANCH (DKKWCA3).

A. Serves as the primary sources for scientific and medical expertise on implantable electrophys 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. CARDIAC ELECTROPHYSIOLOGY DEVICES BRANCH (DKKWCA7).

A. Serves as the primary sources for scientific and medical expertise on cardiac electrophysiology 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. PERIPHERAL INTERVENTIONAL DEVICES BRANCH (DKKWCA9).

A. Serves as the primary sources for scientific and medical expertise on peripheral interventional devices, including implants and tools 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. VASCULAR SURGERY DEVICES BRANCH (DKKWCA11).

A. Serves as the primary sources for scientific and medical expertise on vascular surgery 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.

8. STRUCTURAL HEART DEVICES BRANCH (DKKWCA12).

A. Serves as the primary sources for scientific and medical expertise on structural heart device 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.

9. 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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STAFF MANUAL GUIDE 1253.3
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 Cardiovascular Devices organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Cardiac Diagnostics Devices Branch
- Cardiac Electrophysiology Devices Branch
- Peripheral Interventional Devices Branch
- Implantable Electrophysiology Devices Branch
- Circulatory Support Devices Branch
- Vascular Surgery Devices Branch
- Structural Heart Devices Branch