SMG 1257.5

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 IN VITRO DIAGNOSTICS AND RADIOLOGICAL HEALTH

DIVISION OF RADIOLOGICAL HEALTH

Effective Date: 09/25/2012

1. DIVISION OF RADIOLOGICAL HEALTH (DKKWJD).

A. Serves as the primary source for scientific and medical expertise on radiological devices with regard to safety and effectiveness.

B. Carries out scientific and medical review evaluation for documents related to classification, petitions, 510(k)'s, Humanitarian Device Exemptions (HDEs), premarket approval applications (PMAs), product development protocols (PDPs), investigational device exemptions (IDEs), and all supplements and amendments to these submissions, as authorized.

C. Makes preliminary determinations of equivalence or nonequivalence and of approval or nonapproval for actions related to classification, petitions, 510(k)s, HDEs, PMAs, PDPs, IDEs, and all supplements and amendments to these submissions, as authorized.

D. Provides technical and nontechnical support to device advisory panels and panel members and consultants.

E. Coordinates actions on classification actions, petitions, 510(k)'s HDEs, PMA, PDPs, and IDEs with Center and Agency components or other organizations, when appropriate.

F. Enforces the Medical Device Amendments of 1976 and subsequent medical device laws and regulations affecting in vitro diagnostics and radiological devices; and enforces the Radiation Control for Health and Safety Act of 1972 relating to radiological devices and radiation emitting products.

G. Manages and coordinates activities associated with administrative and regulatory actions for radiological devices and radiation emitting products.

H. Develops and interprets policy guidance in response to specific requests from the medical device and electronic products industries, trade associations, other Federal agencies, other countries, State agencies, and the general public.

I. Develops, reviews, and revises new and amended regulations including good manufacturing practices (GMPs) and standards for electronic products.

J. Plans, initiates and medical device and electronic product inspections and investigations of manufacturers and their products. Reviews and evaluates design, test, and production data and reports from manufacturers to ensure compliance with promulgated standards and regulations.

K. Identifies the need for and directs the development of Compliance Policy Guides and programs to facilitate compliance by manufacturers. Develops, coordinates, reviews, and revises medical device industry GMP regulations. Develops and implements programs to ensure uniform interpretation and application of GMPs and recommends regulatory action when appropriate.

L. Develops and implements techniques and procedures to assess trends in exposure and image quality in diagnostic radiology and identifies and corrects problems through cooperative Federal and State programs.

M. Develops and maintains mechanisms for ongoing liaison and routine communication with Federal, State and local government agencies, with relevant health professional and consumer groups, and with all certified mammography facilities about issues related to the Mammography Quality Standards Act and provides appropriate reports on the Mammography Quality Standards Act to the Department, Congress and the public.

2. MAGNETIC RESONANCE AND ELECTRONIC PRODUCTS BRANCH (DKKWJD1).

A. Serves as the primary source for regulatory, scientific and medical expertise on magnetic resonance devices and electronic products.

B. Coordinates, carries out, and makes preliminary premarket review determinations for magnetic resonance devices related to classification, petitions, 510(k)s, IDEs, PMAs, and PDPs, and all supplements and amendments to these submissions, as authorized.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to magnetic resonance and electronic products.

3. DIAGNOSTIC X-RAY SYSTEMS BRANCH (DKKWJD2).

A. Serves as the primary source for regulatory, scientific and medical expertise on diagnostic x-ray systems.

B. Coordinates, carries out, and makes preliminary premarket review determinations for diagnostic x-ray systems related to classification, petitions, 510(k)s, IDEs, PMAs, and PDPs, and all supplements and amendments to these submissions, as authorized.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to diagnostic x-ray systems.

4. NUCLEAR MEDICINE AND RADIATION THERAPHY BRANCH (DKKWJD3).

A. Serves as the primary source for regulatory, scientific and medical expertise on nuclear medicine and radiation therapy devices.

B. Coordinates, carries out, and makes preliminary premarket review determinations for nuclear medicine and radiation therapy devices related to classification, petitions, 510(k)s, IDEs, PMAs, and PDPs, and all supplements and amendments to these submissions, as authorized.

C. Plans, manages, enforces, develops and interpret postmarket laws, regulations and policies related to nuclear medicine and radiation therapy devices.

5. MAMMOGRAPHY, ULTRASOUND AND IMAGING SOFTWARE BRANCH (DKKWJD4).

A. Serves as the primary source for regulatory, scientific and medical expertise on mammography, ultrasound and medical imaging devices.

B. Coordinates, carries out, and makes preliminary premarket review determinations for mammography, ultrasound and medical imaging devices related to classification, petitions, 510(k)s, IDEs, PMAs, and PDPs, and all supplements and amendments to these submissions, as authorized.

C. Plans, manages, enforces, develops and interprets postmarket laws, regulations and policies related to mammography, ultrasound and medical

imaging devices.

6. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Commissioner of Food and Drugs on September 25, 2013.

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OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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DIVISION OF RADIOLOGICAL HEALTH

OFFICE OF THE DIRECTOR

Magnetic Resonance and Electronic Products Branch
Diagnostic X-Ray Systems Branch
Nuclear Medicine and Radiation Therapy Branch
Mammography, Ultrasound and Imaging Software Branch

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The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health, Division of Radiological Health organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Magnetic Resonance and Electronic Products Branch
- Diagnostic X-Ray Systems Branch
- Nuclear Medicine and Radiation Therapy Branch
- Mammography, Ultrasound and Imaging Software Branch