SMG 1253.1

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

Effective Date: 9/26/2012

1. OFFICE OF DEVICE EVALUATION (DWKKWC).

A. Advises the Center Director and other agency officials on all premarket notification submissions (510(k)s), premarket approval applications (PMAs), product development protocols (PDPs), device classifications, and investigational device exemptions (IDEs).

B. Plans, conducts, and coordinates appropriate Center actions regarding approval, denial, and withdrawal of approval of PMAs, PDPs, IDEs, and makes substantially equivalent determinations for 510(k)s, and monitors sponsors' conformance with requirements of all programs.

C. Conducts a continuing review, surveillance, and medical evaluation of the labeling, clinical experience, and required reports submitted by sponsors of approval applications.

D. Provides executive secretariat and other technical support to medical device advisory panels; recommends establishing or restructuring such panels as appropriate.

E. Develops and interprets regulation and guidelines regarding classification, PDPs, IDEs, PMAs, and 510(k)s.

F. Coordinates Center classification activities; reviews petitions for or initiates reclassification of medical devices.

G. Participates in the development of national and international consensus standards, and voluntary guidelines through interaction with appropriate national and international standards committees.

H. Operates a document control system.

2. 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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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 organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Program Management Staff
- Program Operations Staff
- Premarket Approval Staff
- Investigational Device Exemption Staff
- Premarket Notification Section
- DIVISION OF OPHTHALMIC AND EAR, NOSE AND THROAT DEVICES
- DIVISION OF REPRODUCTIVE, GASTRO-RENAL AND UROLOGICAL DEVICES
- DIVISION OF ORTHOPEDIC DEVICES
- DIVISION OF ANESTHESIOLOGY, GENERAL HOSPITAL, RESPIRATORY INFECTION CONTROL, AND DENTAL DEVICES
- DIVISION OF SURGICAL DEVICES
- DIVISION OF CARDIOVASCULAR DEVICES
- DIVISION OF NEUROLOGICAL AND PHYSICAL MEDICINE DEVICES