**Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90-2 (blue book memo) (Text Only)**

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This guidance was written prior to the February 27, 1997 implementation of FDA’s Good Guidance Practices, GGP’s. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP’s.

**General Program Memorandum #G90-2**

Date: Oct. 19, 1990

From: Director, Office of Device Evaluation (HFZ-400)

Subject: Consolidated Review of Submissions for Diagnostic Ultrasound

Equipment, Accessories, and Related Measurement Devices

To: ODE Review Staff

Purpose. The purpose of this guidance is to promoted uniformity

and efficiency in the review of submissions for Diagnostic Ultrasound

Equipment, Accessories, and Related Measurement Devices. 510(k)

submissions for these devices may have been reviewed in different

divisions depending upon the intended use of a specific device. This

guidance assures the consolidation of responsibility for review of

510(k) submissions and their supporting IDEs for these devices

within one division, while at the same time maintaining inter-

divisional consultations, as necessary, to assure the high level of

expert review that has been applied in the past. This memorandum

clarifies the roles and responsibilities of the primary reviewing

division and the consulting divisions and sets forth the procedures

they will use for this review process.

Identification of Divisions and Devices. The following

divisions and devices are the subject of this memorandum:

- Consolidated Devices: DIAGNOSTIC ULTRASOUND EQUIPMENT,

ACCESSORIES, AND RELATED

MEASUREMENT DEVICES

- Primary Division: DIVISION OF OBSTETRICS/GYNOCOLOGY,

EAR, NOSE, THROAT, AND

DENTAL DEVICES

- Consulting Divisions: ALL ODE DIVISIONS, EXCEPT THE

DIVISION OF CLINICAL LABORATORY

DEVICES

510(K)s and Supporting IDEs.

- The Primary Division wil be responsible for the review of

510(k)s and supporting IDEs for the Consolidated Devices.

- The Consulting Division will provide to the Primary Division

the name of its contact person who will serve as the liaison

with the Primary Division concerning 510(k)s and IDEs for the

Consolidated Devices.

- The Consulting Divisions will provide to the Primary Division

a list of intended uses, i.e., indication statements, for all

Consolidated Devices and their accessories that are subject to

this memorandum and that have been found to be

substantially equivalent via 510(k) decisions including a brief

statement regarding currently required data to support these

decisions. In addition, the Consulting Divisions will also

provide, when applicable, a list of Consolidated Devices that

have approved PMAs and relevant PMA information that will

assist in making 510(k) decisions.

- The Consulting Divisions will provide to the Primary Division

a list of current IDEs that are approved for the purpose of

gathering clinical data in support of a 510(k) for the

Consolidated Devices. These ongoing IDEs will be transferred to

the Primary Division. Future submissions concerning these

IDEs, e.g., amendments, will be reviewed by the Primary

Division. The Primary Division, in turn, will obtain feedback

from the Consulting Divisions, if necessary.

- During the review of 510(k)s for the Consolidated Devices,

the Primary Division will seek input from the Consulting

Divisions whenever necessary, such as when a 510(k) contains

an indication statement that raises the possibility that a new

use may be intended. After a new insicatiion statement has

been approved via the 510 process a few times, the Primary

Division will seek consultation only when deemed appropriate.

- When input is sought from a Consulting Division, all

necessary feedback will be provided to the Primary Division

within 30 days. With respect to "not substantially equivalent"

decisions, the Primary Division will obtain the review and

concurrence of the Consulting Divisions, which will be reflected

in the yellow sign-off sheets.

PMAs and Supporting IDEs.

- As in the past, a PMA and its supporting IDE for a

Consolidated Device will be reviewed by the division

responsible for the medical specialty for whose use the device

is intended. This may be the Primary Division or a Consulting

Division, depending upon the specific device and its intended

use. If the reviewing division for the PMA/IDE is a Consulting

Division, the Primary Division, when requested, will provide

the technical review of these submissions for the reviewing

division.

New IDEs.

- The POS/DMC will send all new IDEs for Consolidated Devices

to both the Primary Division and the Consulting Divisions.

Within two days of receipt of the IDE, the Primary Division and

the Consulting Divisions will meet to decide whether the device is

likely to proceed to market via a 510(k) or PMA. The

Primary Division will be responsible only for 510(k) track IDEs.

The PMA track IDE will be reviewed by the division that will

review the PMA, as discussed above.

Other General Procedures.

- The Primary Division will send copies of all 510(k) and IDE

decision letters to the appropriate Consulting Division at the

time each is issued.

- The Primary Division will conduct monthly or bimonthly

meetings with the Consulting Divisions to provide an update on

the status of reviews and actions taken since the previous

meeting.

- Issues between the Primary Division and the Consulting

Divsions that are not resolved at the review level will be

documented and presented in a timely manner to the affected

division directors for resolution. If any issue cannot be

resolved by the division directors, they will refer the matter to

the Office of the Director, Office of Device Evaluation.

Effective Date. This guidance memorandum is effective immediately.

https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081369.htm