**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