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.

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DRAFT

Necessary Information for Diagnostic Ultrasound 510(k)

A. Acoustic Output

B. Predicate Indications for Diagnostic Ultrasound

C. General Clinical Safety and Effectiveness

D. Contact Persons

Necessary Information for Diagnostic Ultrasound 510(k)

A. Acoustic Output

Acoustic output should be measured and reported per the 510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices issued in December 1985. The following are clarifications of certain aspects of the Guide.

1) Acoustic output should be provided for each operating mode of each transducer with each compatible system. Each output intensity should be compared to the intensity of a comparable preenactment device for each target tissue type to be insonated, per Appendix B of the 510(k) Guide.

2) Each intensity should be given with the corresponding accuracy of that intensity measurement.

3) The **maximum** estimated in situ intensity is to be compared to the preenactment value. This maximum value might not correspond to the maximum intensity measured in water. Therefore, it may be necessary to provide both a maximum water value as well as the water value corresponding to the maximum estimated in situ value.

4) In the methodology section, describe the search technique used to locate the global maximum. Include additional detail and explanation for special cases, such as multi-focal transducers or situations, like that described in #3 above, where it is necessary to locate more than one maximum. In the case of multi-focal transducers, discuss how the measurement methodology ensures that the maximum for each intensity does not occur in another focal zone.

5) Provide representative annotated worksheets to show how measured intensities and the corresponding checkvalues and estimated in situ values are calculated.

6) Provide an explanation for large differences between measured intensities and checkvalues. (See Appendix C of the 510(k) Guide.) If necessary, provide a profile of the beam pattern from that measurement.

B. Predicate Indications for Diagnostic Ultrasound

Below are predicate indications that FDA recognizes to date. For any indication, the labeling should include a full statement of intended use. The statement should specify how the energy is directed and the purpose of the procedure. These statements should take the form: "The (device) projects ultrasound energy through the (anatomical site) of (appropriate person) to obtain an image of (internal structure) that can be used to (purpose)." Following are examples of indication statements that have been found acceptable. (Please note the examples of full statements which are provided by two of the divisions, DANRD and DCD.

1. Division of Anesthesiology, Neurology, and Radiology Devices (DANRD)

1) Echoencephalograph
2) Intracranial Biopsy Procedure (B-mode only)
3) Doppler Blood Flow Detection

Examples:

The echoencephalograph applies ultrasound energy through the intact fontanelles of infants to obtain an image of the brain ventricles that can be used to detect abnormal ventrical size or a shift in the midline.

The Model XX includes accessories that allow ultrasound energy to be applied directly through the exposed dura mater of neurosurgical patients to obtain a image that can be used to guide a biopsy needle.

The ultrasonic Doppler device applies ultrasound energy through the cranium to obtain a Doppler spectrum that shows the approximate velocity of blood in some of the major cranial arteries.

2. Division of Cardiovascular Devices (DCD)

1) Cardiac Imaging
2) Doppler Ultrasound
3) Cardiac Biometry
4) Peripheral Vessel Imaging

Examples:

Imaging

The echocardiograph applies ultrasound energy through the chest wall to obtain an image of the heart structure that can be used to detect abnormalities in the heart.

The echocardiograph applies ultrasound energy through the neck of the patient to obtain an image of the carotid that can be used to detect abnormalities or obstructions in the vessel.

The Model XYZ is a catheter-tipped ultrasound device that applies ultrasound energy directly into the interior vessel wall of the patient to obtain an image of the vessel that can be used to detect abnormalities or obstructions in the vessel. This device is contraindicated for use in coronary vessels.

The Model ZZ device applies ultrasound energy through the esophagus of the patient to obtain an image of the heart structure that can be used to detect abnormalities in the heart.

Doppler

The ultrasonic Doppler device applies ultrasound energy thorough the chest wall to determine the velocity of blood in the heart and vessels.

The ultrasonic Doppler device applies ultrasound energy through the abdomen to determine the velocity of blood in the deep abdominal vessels.

The ultrasonic Doppler device applies ultrasound energy through the leg of the patient to assess the blood velocity, pressure, and patency of peripheral vessels.

The ultrasonic Doppler probe applies ultrasound energy directly to the heart or vessel wall to evaluate the velocity of blood.

Biometry

The Model XX applies ultrasound energy through the chest wall to image and measure anatomic physiologic parameters of the heart and vessels. These measurements include cardiac volume, area, LVEDP volume, ejection fraction,....

3. Division of Gastroenterology, Urology and General Use Devices (DGGD)

1) Abdominal: GI tract, kidney & bladder, etc.
2) Deep abdominal Doppler evaluation of major renal, hepatic, or splanchnic vessels
3) Transrectal: prostate
4) Thyroid
5) Pediatric soft tissue only

4. Division of Ophthalmic Devices (DOD)

1) Corneal thickness and axial length measurements
2) General ophthalmic imaging
3) Ocular foreign body imaging

5. Division of OB-GYN, ENT, and Dental Devices (DOED)

OB-GYN:

1) Fetal heart rate (FHR) monitoring
2) Fetal imaging and/or measurements
3) Breast scanning
4) Transvaginal imaging
5) Follicular growth monitoring
6) General gynecological imaging

Dental/ENT

1) Nasal sinus Scanning and/or measurements

6. Division of Surgical and Rehabilitation Devices (DSRD)

1) Fat skin thickness measurement

C. General Clinical Safety and Effectiveness

1. List a predicate device (and accessories, if applicable) and an intended use statement.

2. Provide the design similarities and differences of the system and/or probe to the predicate device. Relate specific design features to the intended use(s).

3. Provide a tabular comparison of the new device to the predicate device and accessories:

   a. intended use;
   b. patient contact materials; and
   c. imaging resolution or measurement accuracy and precision.

4. Provide a summary of the basic algorithm used for software functions.

   Provide an assurance of proper software design, validation and assurance program.

   Provide a safety feature to protect the patient in the event of a software failure if the acoustic output is controlled by software, (e.g., the acoustic output is limited to a predetermined maximum level.)

   If the device displays a clinical diagnosis of the patient, discuss the basis and/or decision rules of the device. Provide information supporting the effectiveness of the device.

5. Provide the range and accuracy for each clinical parameter measured by the device in the device labeling. For example: Model XX is capable of measuring blood flow velocity between 0 and 5.5 m/sec with an accuracy of $\pm$ 10%.

6. Provide evidence of electrical safety, including the measured leakage current and the mechanism of electrical isolation of the device from the line current.

7. Provide labeling that includes:

   a. operator's manual;
   b. brochures that describe the system and associated transducers;
   c. maximum vater and maximum estimated in situ values for I_{SPTA}, I_{SPPA} and Im intensity parameters for each transducer/mode combination;
   d. explanation of calculated in situ values;
   e. clinical instructions for use;
   f. if not intended for fetal use - in the manual - stated "not intended for fetal use";
   g. intended use, contraindications, varnings and precautions;
   h. for invasive probes - recommended depth of insertion and methods of use;

i. instructions for the care of the device, including cleaning, disinfecting, and sterilization;
j. prescription device labeling statement;
k. range and accuracy of measurement; and
l. references to literature, if appropriate. (If literature is used as part of your labeling, the techniques, methods, and implied use in the literature becomes part of the intended use in your labeling and may need to be supported by clinical data.)

8. If the device produces acoustic output greater than preenactment levels, employs new intended uses, or adapts new accessories, clinical studies may be necessary. Contact the individual Division contact person (See section D.), if there is any question concerning intended use or the requirements for clinical studies.

9. Division Specific Questions

1. DANRD

If the intended use is for anything other than detecting the velocity of blood in an artery, the intended use must be defined and supported by clinical data.

If the device labeling allows transorbital use, specific directions limiting power output must be provided.

Discuss the degree to which pyrogenicity is avoided for any device surface that makes subdural contact.

Application through the fontanelles or the temporal window must consider the effects of insonating the posterior aspect of the orbit. (A caution statement in the labeling may be necessary.)

2. DCD

If diagnostic indications for use are made in the labeling or instruction manual, e.g. diagnosis of stroke, aortic stenosis, etc., clinical data must be provided to support the indicated use.

3. DOED

The labeling for ultrasound transducers may not purport or represent the device to be safe and effective for <u>in vitro</u> fertilization (IVF).

Transducers or systems intended for breast evaluation may not be labeled for detection or diagnosis of breast cancer without supporting clinical data.

D. Contact persons

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Questions on the review of acoustic output and use of the 510(k) Guide should be directed to Mr. Colin M. Pollard at (301) 427-7555. Overall questions on 510(k) procedures may be directed to Mr. Robert I. Chissler at (301) 427-8162 or Lillian Yin, Ph.D., at (301) 427-7555.