Guidance for Industry

Harmonic Imaging with/without Contrast – Premarket Notification Requirements

Document issued on: November 16, 1998

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Radiology Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Robert Phillips, Ph.D., HFZ-470, (240) 276-3666, 9200 Corporate Boulevard, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Robert Phillips at RobertA.Phillips@fda.hhs.gov.

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World Wide Web/CDRH home page: http://www.fda.gov/cdrh/ode/harmonic.pdf, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2234 when prompted for the document shelf number.

November 6, 1998

To: Manufacturers of Ultrasound Imaging Devices

Re: Harmonic Imaging with/without Contrast – Premarket Notification Requirements

When harmonic imaging was first introduced, it was presented as a method to improve the signal to noise ratio of an ultrasound image. The first ultrasound imaging devices to use harmonic imaging did it with a contrast agent. Later, manufacturers were able to demonstrate that some harmonic imaging products were capable of producing quality images without the need for a contrast agent. Based on this new information, some manufacturers were cleared to market ultrasound imaging devices for harmonic imaging without contrast.

Currently, the Center for Devices and Radiological Health (CDRH) receives and clears 510(k) submissions for devices that perform conventional ultrasound imaging (i.e., using the fundamental frequency of the transducer) as well as harmonic imaging with and without contrast agents.

The Center for Drug Evaluation and Research (CDER) approves marketing applications for ultrasound contrast agents, for use in both conventional and harmonic imaging. Its review process establishes the safety and efficacy of the contrast agent when used with a conventional or harmonic imager. Therefore, the CDER review of the contrast agent with harmonic imaging duplicates many aspects of the CDRH review of harmonic imaging with CDER approved contrast agents.

To avoid any unnecessary duplication of effort, CDRH has determined that manufacturers of ultrasound devices cleared for harmonic imaging without contrast agent do not need to submit 510(k)s to add the use of contrast to their labeling. As in the past, 510(k) clearance is required for new ultrasound imaging devices or to significantly modify existing devices. A labeling change to add harmonic imaging without contrast is a significant change that warrants a 510(k) clearance.

This change is effective immediately.

If you have any questions, please contact Robert Phillips, Ph.D., at 301-594-1212.

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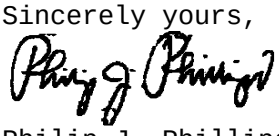
Sincerely yours,



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