DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Ms. Margret J. Larson
President
SonoTech, Inc.
77 Marine Drive
BELLINGHAM WA 98227-2189

Re: K042619
Trade/Device Name: UltraBio – In Vivo Biocompatible Bioeliminated Sterile Ultrasound Imaging Couplant
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 MUI
Dated: October 14, 2004
Received: October 18, 2004

Dear Ms. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: UltraBio - In Vivo Biocompatible, Bioeliminated Sterile Ultrasound Imaging Couplant

Indications For Use:

UltraBio, as an in vivo biocompatible and bioexcretable sterile couplant, is intended to replace sterilized transcutaneous scanning gels that are not in vivo biocompatible or in vivo bioexcretable, but that are commonly used in surgical procedures, biopsies and similar sterile applications.

UltraBio will be used to couple sound waves between the patient and medical imaging electronic transducers during intraoperative and intracavitary medical diagnostic ultrasound imaging procedures. It will be used with transcutaneous ultrasound image guided biopsy and aspiration, intraoperative ultrasound imaging, and intracavity ultrasound imaging.

UltraBio is unit dose packaged, sterilized and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or fluid alone or in combination with a latex, polyurethane or polyethylene transducer cover where sterility and in vivo biocompatibility and bioelimination are required.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012619