DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1999

Margaret J. Larson
President
Sonotech, Inc.
P.O. Box 2189
Bellingham, WA 98227-2189

Re: K983985
HybriSonic Sheath
Dated: January 7, 1999
Received: January 20, 1999
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Ms. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SONOTECH

Sonotech, Inc.
774 Marine Drive, Bellingham, WA 98225
360/671-9121 fax: 360/671-9024

Registration # 2523891

510(k) Application: **HybriSonic Sheath**

510(k) Number (if known): K983985

Device Name: HYBRISONIC SHEATH

Indications For Use:

Couplant: **HybriSonic Sheaths** will be used during invasive medical diagnostic ultrasound imaging to couple sound waves between the patient's body and medical imaging electronics, provide lubrication and act as a microbial barrier. **HybriSonic Sheaths** are intended for use in sterile and non-sterile fields, including intraoperative, endocavity or transcutaneous ultrasound imaging procedures which currently use an ultrasound coupling gel or fluid alone or in combination with a latex, polyurethane or polypropylene protective transducer cover. The **HybriSonic Sheath** is sufficiently lubricous to be used without additional lubrication for transcutaneous ultrasound such as ultrasound guided biopsy and aspiration.

Microbial barrier: **HybriSonic Sheaths** are also intended for use as ultrasound transducer microbial barriers that are in vivo biocompatible with tissue and body fluids and leave no residue after use, as they remain with the transducer, are single use and disposable.

Device lubricant: In addition to coupling ultrasound, the **HybriSonic Sheath** is intended for use as a device lubricant and microbial barrier during transcutaneous ultrasound exams and with intraoperative ultrasound, endocavitary ultrasound imaging and transcutaneous ultrasound guided biopsy or aspiration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983985

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)