



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2003

Ms. Margaret J. Larson
SONOTECH, Inc.
774 Marine Drive
BELLINGHAM WA 98225

Re: K031222
Trade/Device Name: ScanLube™
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic
transducer
Regulatory Class: II
Product Code: 90 MUI
Dated: July 10, 2003
Received: July 14, 2003

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 (PMA), it may be subject to 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.

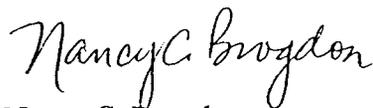
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031222

Device Name: SCANLUBE - IN VIVO BIOCOMPATIBLE STERILE ULTRASOUND IMAGING
COUPLANT AND LUBRICANT

Indications For Use:

ScanLube is an in vivo biocompatible and biodegradable sterile ultrasound couplant that will be used in conjunction with hydrogel pads, such as Sonotech's ScanTac Pad, during medical diagnostic ultrasound imaging to couple ultrasound waves between the patient and medical imaging electronics.

ScanLube converts an adhesive hydrogel surface into a lubricous surface by hydrogen bonding with the ScanTac Pad, which then facilitates scanning with an ultrasound transducer.

ScanLube is intended for use with the ScanTac Strip and ScanTac Pad in conjunction with transcutaneous ultrasound image guided biopsy and aspiration, and within a protective sheath (probe cover) for intraoperative and endocavity ultrasound imaging.

ScanLube, when swabbed or similarly applied to the exposed surface of a hydrogel strip, such as the ScanTac Strip, when attached to the face of a transducer, converts the exposed hydrogel adhesive surface to lubricous, thus enabling the easy insertion of the hydrogel covered transducer into a transducer cover or sheath, or for scanning the patient using direct contact of the lubricous hydrogel surface.

ScanLube is unit dose packaged, sterilized and intended for use as a couplant and lubricant in all diagnostic ultrasound procedures which 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 are required.

ScanLube may be used to lubricate the exterior surface of endocavity transducer sheaths or covers prior to insertion into the vagina or rectum. In this application, ScanLube serves both as an ultrasound couplant and instrument lubricant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031222