

K981028

SONOTECH, INC.

774 Marine Drive Bellingham, WA 98225

Registration #2523891

510(k) Number K981028

Sono Image and Ultra Glide

AUG 21 1998

510(k) SUMMARY - #K981028

as required by 807.92(c)

SONOTECH, INC.

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Bellingham, WA 98225

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Contact person: Margaret J. Larson

Date Prepared: August 3, 1998

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Sono Image and Ultra Glide

General Information

Reason for Premarket Notification: New device

Trade name of device: Sono Image and Ultra Glide

Common or usual name: Medical diagnostic ultrasound scanning gel

Regulatory Classification: II

Legally marketed devices to which we claim equivalence (see Comparison Table for further information):

Natural Image Scanning Gel, K883917/B, reviewed and clearance received 3/31/89

Clear Image Sterile Scanning Gel, K931909, reviewed and clearance received 3/21/94

SonoMix Scanning Gel, K931908/SI, reviewed and clearance received 12/13/94

Description: Sono Image and Ultra Glide are medical diagnostic ultrasound scanning gels that transmit sound waves into the body through the skin and whose formulas are identical except for the polymer (thickener) content. Sono Image and Ultra Glide do not contain silicon, mineral oil, surfactants or any chemicals which are considered harmful to ultrasound transducer material (see Sono Image and Ultra Glide product formulation).

Intended Use: Sono Image and Ultra Glide are coupling gels and will be used in conjunction with ultrasound transducers during medical diagnostic ultrasound to couple sound waves into the patient's body. Sono Image is a high viscosity scanning gel suitable for echocardiography, vascular sonography and general ultrasound scanning procedures. Ultra Glide is a low viscosity scanning gel suitable for abdominal, OB/GYN and general ultrasound scanning procedures.

Note: viscosity does not affect the safety or performance of a scanning gel. Scanning gels are selected by sonographers based on viscosity preference.



AUG 21 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Katie Monty
Products and Sales Manager
Sonotech, Inc.
P.O. Box 2189
Bellingham, WA 98227-2189Re: K981028
Sono Image and Ultra Glide
Dated: July 29, 1998
Received: August 6, 1998
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Ms. Monty:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981028

Device Name: SONO IMAGE & ULTRA GLIDE

Indications For Use:

Sono Image and Ultra Glide are coupling gels and will be used in conjunction with ultrasound transducers during medical diagnostic ultrasound to couple sound waves into the patient's body.

Sono Image is a high viscosity scanning gel suitable for echocardiography, vascular sonography, vascular sonography and general ultrasound scanning procedures.

Ultra Glide is a low viscosity scanning gel suitable for abdominal, OB/GYN and general ultrasound scanning procedures.

Note: viscosity does not affect the safety or performance of a scanning gel. Scanning gels are selected by sonographers based on viscosity preference.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Reynolds
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981028

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use