K 130041

Section 5:
510(K) Summary

FEB 0 6 2013

(As required by 21 CFR 807.92)

Sterile Ultrasound Gel

January 30, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

To Whom it may Concern:

This letter, along with the attached materials is to notify your office of the intention of Sheathing Technologies to market the following device starting on or after (90) days from this date.

Classification:	The FDA has classified ultrasound gel as a Class II device in the Code of Federal Regulations (CFR) 892.1570, Diagnostic ultrasonic transducer.
Classification Panel:	Radiology
Classification Procode:	MUI
Device/Specification Developer:	Sheathing Technologies, Inc. 18431 Technology Drive Morgan Hill, CA 95037
Establishment Registration No.:	2950776
Contact Persons:	Jennifer Downing Manager of Quality & Research

1-408-782-2720

Richard Stevens
VP, Research & Development
1-408-782-2720

Trade Name:	Sheathes™ Sterile Ultrasound Gel
Common Name:	Sterile Ultrasound Gel
Classification Name:	Ultrasonic pulsed echo imaging system accessory
Equivalence:	Sonotech Clear Image™ Sterile Scanning Gel, K931909 Sheathing Technologies Ultrasound Gel, K112827 Sonotech UltraBio™ Sterile Ultrasound Imaging Couplant, K042619.
Labeling and Usage:	The following information will be found on each box/bag: 1. Proprietary name 2. Quantity of gel 3. Name and Location of Manufacturer 4. Statement of Sterility 5. Expiration date 6. Prescription Statement: "Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use."
Device Description:	Sheathing Technologies, Inc Ultrasound Gel is a water-based coupling agent for diagnostic ultrasonic procedures. This device is an accessory used on diagnostic ultrasound probes. The material is a water-based gel. Gel will be sold in sterile packets for single patient/procedure, disposable use.

Substantial Equivalence: The Sheathing Technologies, Inc. Ultrasound gel is identified as substantially equivalent to Sonomed/Sonotech's Clear Image Sterile Scanning Gel, K931909, to Sheathing Technologies's Ultrasound Gel, K112827, and to Sonotech/Sonomed's UltraBio Sterile Ultrasound Imaging Couplant, K042619.

Non-Clinical Tests:

1. Biocompatibility
   a. Cytotoxicity
   b. Irritation/Intracutaneous Toxicity
   c. Sensitization
2. Bench testing
   a. Sound Velocity
   b. Acoustic Impedance
   c. Sound Attenuation
3. Physical measurements
   a. Viscosity
   b. Density

Conclusions from Non-Clinical Tests: Sheathing Technologies's ultrasound gel meets the ISO 10993-1:2009 biocompatibility standard for both Irritation/intracutaneous toxicity and sensitization. The cytotoxicity of the ultrasound gel is equivalent to the cytotoxicity Sonotech's Natural Image Couplant.
Sheathing Technologies's ultrasound gel has equivalent acoustical performance to the predicate Sheathing Technologies gel and to the UltraBio™ predicate gel, and the density and viscosity are within the range measured in the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2013

Sheathing Technologies, Inc
c/o Jennifer Downing
Senior Manager of Quality & Research
18431 Technologies Inc.
MORAN HILL CA 95037

Re: K130041
Trade/Device Name: Sterile Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: January 5, 2013
Received: January 8, 2013

Dear Ms. Downing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Ultrasound Gel

Indications for Use: Sterile ultrasound couplant for use with medical diagnostic ultrasound. It is intended for non-invasive use in medical diagnostic ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gel is intended for use in all diagnostic ultrasound procedures which require ultrasound coupling gel or fluid.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130041