K112827

Section 5:
510(K) Summary

JUN 22 2012

(As required by 21 CFR 807.92)

Ultrasound Gel

June 13, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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.

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™ Ultrasound Gel
Common Name:	Ultrasound Gel

Classification Name:	Ultrasonic pulsed echo imaging system accessory
Equivalence:	Sonotech Natural Image Ultrasonic Couplant, 510K#K883917 Konix Ultrasound Gel, 510K#K101952
Labeling and Usage:	The following information will be found on each box/bag . (See Attachment E): 1. Proprietary name 2. Quantity of gel 3. Name and Location of Manufacturer 4. Expiration date 5. 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. Product categories/models include 1. Individual packets (non-sterile) 2. Bulk bottles (non-sterile) Gel is for single patient/procedure, disposable use.
Substantial Equivalence:	The Sheathing Technologies, Inc. Ultrasound gel is identified as substantially equivalent to Sonomed/Sonotech's Natural Image Ultrasound Couplant, 510K#K883917, and to Konix Ultrasound Gel, 510K#K101952.

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 (toxicology report is attached.)

Sheathing Technologies's ultrasound gel has equivalent acoustical performance to the predicate Konix Ultrasound 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 Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2012

Ms. Jennifer Downing
Senior Manager of Quality & Research
Sheathing Technologies, Inc.
18431 Technology Drive
MORGAN HILL CA 95037

Re: K112827
Trade/Device Name: Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: June 13, 2012
Received: June 14, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4:
Indications for Use Statement

510(k) Number (if known):

Device Name: Ultrasound Gel

Indication For Use: Non-sterile ultrasound couplant for use with medical diagnostic ultrasound. It is intended to be used during non-invasive 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 ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K112827