



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

Sheathing Technologies, Inc.
% Ms. Jennifer Downing
SR MGR of Quality & Research
18431 Technology Drive
MORGAN HILL CA 95037

March 4, 2016

Re: K153212
Trade/Device Name: Sheathes Ultrasound Probe Covers
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: February 9, 2016
Received: February 11, 2016

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

A handwritten signature in blue ink that reads "Robert D. O'Hara". The signature is written over a large, light gray watermark of the FDA logo.

FOR

Robert Ochs, Ph.D.
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)
K153212

Device Name
Sheathes Ultrasound Probe Covers

Indications for Use (Describe)

The intended use of the device is identical to the predicate 510(k) K990175 except for the removal of the word 'sterile' (as the device may be sold either sterile or non-sterile), and the change of 'Latex-Free', per current FDA guidance against using this term, to 'Polyurethane':

Indications for Use: Polyurethane probe covers are indicated during diagnostic ultrasound procedures in cases where patient sensitivity to latex is speculative.

Contraindications: Polyurethane probe covers are contraindicated during diagnostic ultrasound procedures in cases where patients exhibit a history of hypersensitivity to the material components.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Office of Chief Information Officer
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Section 7: 510(K) Summary

(As required by 21 CFR 807.92)

Polyurethane Ultrasound Probe Cover

March 1st, 2016

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 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.

Device/Specification Developer: Sheathing Technologies, Inc.
18431 Technology Drive
Morgan Hill, CA 95037

Establishment Registration No.: 2950776

Contact Persons: Jennifer Downing
Chief of Technology, Quality, and Regulatory
Affairs
1-408-782-2720x12

Richard Stevens
VP of Research & Development
1-408-782-2720x14

Trade Name: Sheathes Ultrasound Probe Covers

Common Name:	Ultrasound Probe/Transducer Cover/Sheath/Drape
Classification Name:	TRANSDUCER, ULTRASONIC, DIAGNOSTIC
Classification:	The FDA has classified probe covers as a Class II device in the Code of Federal Regulations, (CFR) 892.1570
Classification Panel:	Radiology
Classification Procode:	ITX
Equivalence:	This 510(k) is equivalent to Sheathing Technologies's previously cleared K990175, Sheathes Non-Latex Ultrasound Probe Covers.
Indications for Use:	<p>The intended use of the device is identical to the predicate 510(k) K990175 except for the removal of the word 'sterile' (as the device may be sold either sterile or non-sterile), and the change of 'Latex-Free', per current FDA guidance against using this term, to 'Polyurethane':</p> <p>Indications for Use: Polyurethane probe covers are indicated during diagnostic ultrasound procedures in cases where patient sensitivity to latex is speculative.</p> <p>Contraindications: Polyurethane probe covers are contraindicated during diagnostic ultrasound procedures in cases where patients exhibit a history of hypersensitivity to the material components.</p>
Labeling and Usage:	<p>The following information will be found on each box/bag . (See Section 13, Proposed Labeling):</p> <ol style="list-style-type: none"> 1. Proprietary name 2. Quantity of sheathes packed 3. Name and Location of Manufacturer 4. Sterile/NS (if applicable)

5. Expiration date
6. Size of probe cover
7. Caution statements: Follow manufacturer's instructions for cleaning and disinfecting the transducer.
8. 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:

The Sheathing Technologies, Inc Ultrasound Probe Cover provides a thin, conformal covering to fit various and specific ultrasound transducer shapes. The cover is made in a general cylindrical shape. It is closed at the proximal end and open at the distal end for insertion of the ultrasound transducer. This device is an accessory used on diagnostic probes to help minimize cross contamination. The cover material is a polyether-based polyurethane. Various sizes and shapes of covers are offered to address the variations in Ultrasound Transducer configurations.

Product categories/models include

1. General Purpose Sheathes Ultrasound Probe Covers (sterile and non-sterile)

Covers are packaged in both sterile and non-sterile, individually wrapped or in bag/box quantities.

The sole difference between this device and the predicate is a labeling change (addition of "viral barrier" to labeling, based on bench testing) to our line of seamless and seamless-tipped ultrasound probe covers. Please see section 13, labeling, for full wording. Please note that seamless and seamless-tipped probe covers are only a subset of the product line. The labeling for the remaining products would remain unchanged.

Substantial Equivalence: This 510(k) is equivalent to Sheathing Technologies' previously cleared 510(k), K990175, Non-Latex Ultrasound Probe Covers.

Clinical Tests: No clinical tests were performed on the device.

Non-Clinical Tests:

1. Bench Testing:
 - a. Viral Penetration Testing using Minute Mouse Virus
 - b. Burst Testing
 - c. Tensile Testing
 - d. Tear Propagation and Tear Resistance testing
 - e. Leak testing

Conclusions from Non-Clinical Tests: The seamless probe cover device provides a viral barrier to viruses of the size of Minute Mouse Virus (20 nm) or larger.

Based on bench testing, the device is substantially equivalent or superior to the predicate device, and is safe and effective for its intended use.