HR Pharmaceuticals, Inc.
℅ Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

June 13th, 2018

Re: K181363
Trade/Device Name: EcoVue® Sterile and Non-Sterile Ultrasound Gels
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: May 18, 2018
Received: May 23, 2018

Dear Mr. Job:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181363

Device Name
EcoVue® Sterile and Non-Sterile Ultrasound Gels

Indications for Use *(Describe)*
EcoVue® Sterile and Non-Sterile Ultrasound Gels are ultrasound couplants intended to be used on intact skin during non-invasive medical ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gels are intended for use in all diagnostic ultrasound procedures which require coupling gel or fluid.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5.0 510(k) SUMMARY

510(k) SUMMARY
for
EcoVue® Sterile and Non-Sterile Ultrasound Gels

I. SUBMITTER:

HR Pharmaceuticals, Inc.
2600 Eastern Boulevard, Suite 201
York, PA 17402

Telephone Number:717-252-1110 x104
Fax Number:717-685-2590

Contact Person: Colby Wiesman
Date Prepared:04/26/2018

II. DEVICE:

Name of Device: EcoVue® Sterile and Non-Sterile Ultrasound Gels
Common or Usual Name: Media, Coupling, Ultrasound
Classification Name: Diagnostic ultrasonic transducer (21 CFR 892.1570)
Regulatory Class: II
Product Code: MUI

III. PREDICATE DEVICES:

SHEATHING TECHNOLOGIES, Sheathes™ Sterile Ultrasound Gel, K130041
SHEATHING TECHNOLOGIES, Sheathes™ Ultrasound Gel, K112827

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION:

The proposed device, EcoVue® Sterile and Non-Sterile Ultrasound Gels, are non-irritating, non-sensitizing acoustic couplants intended for use as a scanning gel in medical diagnostic ultrasound procedures. The gel is an accessory used to couple sound waves between the patient and the medical imaging electronic transducers during diagnostic ultrasound procedures.

Ultrasound gel is a type of conductive medium that enables a tight bond between the skin and the probe or transducer, allowing the waves to transmit directly to the tissues beneath and to the parts that need to be imaged. As such, the gel is formulated to serve as a lubricant and improve the acoustic transmission of sound waves to create the ultrasound image.

The proposed device is available in the below sizes:

- EcoVue® Ultrasound Gel 20g Sterile SafeWrap™ (REF 280); individual, single-use packet
- EcoVue® Ultrasound Gel 20g Non-Sterile Packet (REF 281); individual, single-use packet
- EcoVue® Ultrasound Gel 250g Non-Sterile FlexPac™ (REF 285); multi-use pouch

V. INDICATIONS FOR USE:

EcoVue® Sterile and Non-Sterile Ultrasound Gels are ultrasound couplants intended to be used on intact skin during non-invasive medical ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gels are intended for use in all diagnostic ultrasound procedures which require coupling gel or fluid.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES:

The subject and predicate devices have the same technological principle whereby, the gel is an accessory to the medical imaging equipment acting as a conductive medium that promotes a tight bond between the skin and the transducer, allowing the waves to transmit directly to the body tissues beneath and to the parts that need to be imaged. As such, ultrasound gels are formulated to act as a coupling agent and reduce static.

At a high level, the EcoVue® Ultrasound Gels and the predicate devices are based on the following same elements:

- Same Intended Use
- Same Technological Characteristics
- Similar Physical Characteristics
- Similar Performance Specifications
- Packaged in similar quantities
- Provided in both sterile and non-sterile product offerings
- Biocompatible
- Water-based gels

While the indications for use for the subject and predicate devices are not identical, they are similar for purposes of substantial equivalence. The only difference is the indications for use for the subject device clarify that the device is for intact skin since non-invasive procedures can involve both intact skin and compromised skin. This clarification is supported by the biocompatibility testing successfully performed on the subject device and does not impact the safety or effectiveness when the subject device is used as intended.

Additionally, side-by-side testing confirmed that the subject devices are substantially equivalent to the predicate devices. A more detailed comparison of the predicate and subject devices is presented in the table below.

		Proposed Device **EcoVue® Sterile and Non-Sterile Ultrasound Gels**	**Predicate Device** **Sheathes Sterile Ultrasound Gel (K130041)**	**Predicate Device** **Sheathes Ultrasound Gel (K112827)**
Manufacturer		HR Pharmaceuticals, Inc.	Sheathing Technologies, Inc.	Sheathing Technologies, Inc.
Device Name		Media, Coupling, Ultrasound	Media, Coupling, Ultrasound	Media, Coupling, Ultrasound
Description		Diagnostic ultrasonic transducer (accessory)	Diagnostic ultrasonic transducer (accessory)	Diagnostic ultrasonic transducer (accessory)
Medical Specialty		Radiology	Radiology	Radiology
Product Code		MUI	MUI	MUI
Reg Number		892.1570	892.1570	892.1570
Class		2	2	2
Indications for Use		EcoVue® Sterile and Non-Sterile Ultrasound Gels are ultrasound couplants intended to be used on intact skin during non-invasive medical ultrasound procedures to couple sound waves between a patient and the medical imaging electronics. The gels are intended for use in all diagnostic ultrasound procedures which require coupling gel or fluid.	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.	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.
Patient-contacting material		Water-based gel (sterile and non-sterile)	Water-based gel (sterile)	Water-based gel (non-sterile)
Sizes		20g individual packets (both sterile and non-sterile) 250g pouch (non-sterile)	20ml individual packets (sterile)	20ml individual packets (non-sterile) Bulk bottle (non-sterile)
Physical and Chemical Properties	Appearance	Clear to Hazy Color; free from foreign matter	Clear or Blue Color	Clear or Blue Color
	Sound Velocity (Acoustic Velocity)	1398-1750 m/s	1591 m/s*	1587 m/s*

		Proposed Device **EcoVue® Sterile and Non-Sterile Ultrasound Gels**	**Predicate Device** **Sheathes Sterile Ultrasound Gel (K130041)**	**Predicate Device** **Sheathes Ultrasound Gel (K112827)**
	Acoustic Impedance	1.40-1.80 Mrayl	1.63 Mrayl*	1.63 Mrayl
	Sound Attenuation	0.32-0.95 dB/cm at 5 MHz 0.65-1.10 dB/cm at 7.5 MHz 0.85-1.55 dB/cm at 10 MHz	0.82 dB/cm at 5 MHz* 1.16 dB/cm at 7.5 MHz* 1.46 dB/cm at 10MHz*	0.90 dB/cm at 5 MHz* 1.57 dB/cm at 7.5 MHz* 2.19 dB/cm at 10MHz*
	Viscosity	>35,000 cP	96,700*	93,700*
	Density	0.85-1.15 g/cm^3	1.027 g/cm^3*	1.026 g/cm^3*
	pH	5.5 – 7.8	6.7*	6.7*
Biocompatibility		Meets ISO 10993-1:2009 requirements for irritation, sensitization, and cytotoxicity	Meets ISO 10993-1:2009 requirements for irritation/intracutaneous toxicity, sensitization, and cytotoxicity	Meets ISO 10993-1:2009 requirements for irritation/intracutaneous toxicity, sensitization, and cytotoxicity
Utility		Single-Use (20g sterile and non-sterile packets) Multi-Use (250g pouch)	Single-Use (20ml sterile packets)	Single-Use (20ml sterile and non-sterile packets) Multi-Use (bulk bottle)
Sterility (Method)		Sterile (Gamma); Non-Sterile	Sterile (Hot Water)	Non-Sterile
Environment of Use		Healthcare Facility	Healthcare Facility	Healthcare Facility
Target Population		Adult and Pediatric	Adult and Pediatric	Adult and Pediatric
Labeling		Prescription Use	Prescription Use	Prescription Use
Shelf Life		1 year	3 years	5 years

*Values obtained from performance testing conducted per HR Pharmaceuticals' protocols.

VII. PERFORMANCE DATA

There are no FDA device-specific guidance documents, special controls document, and/or requirements in a device-specific regulation for acoustic coupling gels. Additionally, no performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for acoustic coupling gels as they are accessories to diagnostic ultrasonic medical devices. However, the EcoVue Ultrasound Gels met the acceptance criteria for the following performance testing to support a substantial equivalence determination.

Bench Testing

- Sound Velocity (Acoustic Velocity) per internal method
- Acoustic Impedance per internal method
- Sound Attenuation per internal method
- Viscosity per ASTM D445 – 17a
- Density per internal method
- pH per internal method
- Antimicrobial Effectiveness per USP <51>
- Sterility per USP <71>
- Microbiological Growth per USP <61>
- Appearance per internal method (both gel and packaging)

Biocompatibility Testing

The biocompatibility evaluation for the EcoVue® Ultrasound Gel was conducted in accordance with the FDA Final Guidance "Use of International Standard ISO-10993, 'Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process,'" June 16, 2016, and International Standard ISO 10993-1:2009 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The biocompatibility testing included the following and yielded acceptable results:

- **Cytotoxicity** - ANSI/AAMI/ISO 10993-5:2009 (R) 2014 Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity
- **Irritation** - ANSI/AAMI/ISO 10993-10:2010 (R) 2014—Biological Evaluation of Medical Devices-Part 5: Tests for Irritation and Skin Sensitization
- **Sensitization** - ANSI/AAMI/ISO 10993-10:2010 (R) 2014—Biological Evaluation of Medical Devices-Part 5: Tests for Irritation and Skin Sensitization

The EcoVue® Ultrasound Gels fall into the category of limited (<24 hour) contact surface devices and are intended for direct contact with intact skin.

Sterilization

EcoVue® Sterile Ultrasound Gel was validated for sterilization using gamma irradiation at a minimum dose of 27.5kGy and a maximum dose of 45kGy to achieve a Sterility Assurance Level of 10^{-6} in accordance with the following recognized standards:

- ANSI/ AAMI/ISO 11137-1:2006/(R) 2010. Sterilization of health care products - Radiation-Part1: Requirements for development validation, and routine control of a sterilization process for medical devices.
- ANSI/AAMI/ISO 11137-2:2013. Sterilization of health care products- Radiation-Part 2: Establishing the sterilization dose.
- ANSI/AAMl/ISO 11137-3:2006 (R) 2010. Sterilization of healthcare products - Radiation-Part 3: Guidance on dosimetric aspects.
- ANSI/AAMl/ISO 11737-1: 2006/(R) 2011. Sterilization of health care products, Microbiological Methods-Part l: Determination of a population of microorganisms on product.
- ANSI/AAMI/ISO 11737-2: 2009. Sterilization of Medical Devices- Microbiological Methods-Part 2: Tests of sterility Performed in the definition, validation and maintenance of a sterilization Process.
- AAMI TIR 17-2008. Compatibility of Materials subject to sterilization.
- ANSI/AAMI/ISO TIR13004: 2013. Sterilization of health care products- Radiation-Substantiation of a selected sterilization dose-Method VDmax^{SD}.

Packaging Validation and Shelf Life

The EcoVue® Sterile and Non-Sterile Ultrasound Gels underwent packaging validation testing and accelerated aging testing per the below standards in order to support a one year shelf life.

- AAMI/ ISO 11607-1: 2006 (R) 2010, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.
- ASTM F2096-11, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak).
- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

VIII. CONCLUSION

All necessary testing has been performed on the EcoVue® Sterile and Non-Sterile Ultrasound Gels to support substantial equivalence. Additionally, the side-by-side performance testing concluded that the subject devices are substantially equivalent to the legally marketed predicate devices.