December 15, 2023

Jianerkang Medical Co., Ltd
% Gu Mike
RA Manager
Suzhou Device Innovation Medical Consulting Co., Ltd
Room 1001, Building 19, No. 3188 Renmin Road
Suzhou, Jiangsu 215000
CHINA

Re: K232957
Trade/Device Name: Sterile and Non-Sterile Ultrasound Gels
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: MUI
Dated: September 21, 2023
Received: September 21, 2023

Dear Gu Mike:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232957

Device Name
Sterile and Non-Sterile Ultrasound Gels

Indications for Use *(Describe)*
Sterile and Non-Sterile Ultrasound Gels is intended to be used on external, intact skin as a coupling contact medium for ultrasonic procedures. The sterile Ultrasound Gel is also used for intra operative, biopsy applications. The Ultrasound Gel can be used during the procedures that involved adults and pediatrics in professional healthcare facility by qualified and trained healthcare professional.

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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510(k) SUMMARY
For K232957
Sterile and Non-Sterile Ultrasound Gels

I. SUBMITTER:

Jianerkang Medical Co., Ltd.
No.1 Jianerkang Road, Zhixi Town Industrial Zone, Jintan District, Changzhou City, Jiangsu Province, China

Telephone Number: 86-519-82446609
Fax Number: 86-519-82442535

Contact Person: Hongfang Tang
Date Prepared: 09/30/2023

II. DEVICE:
Name of Device: 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:

HR Pharmaceuticals, Inc., EcoVue® Sterile and Non-Sterile Ultrasound Gels, K181363

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION:

The proposed device, 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 improve the acoustic transmission of sound waves to create the ultrasound image.

The proposed device is available in the below sizes:

- Tubes 2.2OZ （non sterile）
- Pouches 20ml (sterile)
- Bottles 8.5OZ, 5000ml（non sterile）

V. INDICATIONS FOR USE:

Sterile and Non-Sterile Ultrasound Gels is intended to be used on external, intact skin as a coupling contact medium for ultrasonic procedures. The sterile Ultrasound Gel is also used for intra operative, biopsy applications. The Ultrasound Gel can be used during the procedures that involved adults and pediatrics in professional healthcare facility by qualified and trained healthcare professional.

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 proposed 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

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 (K181363)**
Manufacturer		Jianerkang Medical Co., Ltd	HR Pharmaceuticals, Inc.
Device Name		Media, Coupling, Ultrasound	Media, Coupling, Ultrasound
Description		Diagnostic ultrasonic transducer (accessory)	Diagnostic ultrasonic transducer (accessory)
Medical Specialty		Radiology	Radiology
Product Code		MUI	MUI
Reg Number		892.1570	892.1570
Class		2	2
Indications for Use		Sterile and Non-Sterile Ultrasound Gels is intended to be used on external, intact skin as a coupling contact medium for ultrasonic procedures. The sterile Ultrasound Gel is also used for intra operative, biopsy applications. The Ultrasound Gel can be used during the procedures that involved adults and pediatrics in professional healthcare facility by qualified and trained healthcare professional.	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.
Patient-contacting material		Water-based gel (sterile and non-sterile)	Water-based gel (sterile)
Sizes		Tubes 2.2OZ （non sterile） Pouchs 20ml (sterile) Bottle 8.5OZ, 5000ml（non sterile）	20g individual packets (both sterile and non-sterile) 250g pouch (non-sterile)
Physical and Chemical Properties	Appearance	Colorless or light transparent gel, no or only a few bubbles, non-soluble foreign bodies	Clear to Hazy Color; free from foreign matter
	Sound Velocity (Acoustic Velocity)	1520～1620m/s	1398-1750 m/s

		Proposed Device **EcoVue® Sterile and Non-Sterile Ultrasound Gels**	**Predicate Device** **Sheathes Sterile Ultrasound Gel (K181363)**
	Acoustic Impedance	$1.5\times10^6\sim1.7\times10^6$	1.40-1.80 Mrayl
	Sound Attenuation	≤0.1dB/(cm.MHz)	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
	Viscosity	≥4000 cP (1000 Cp=1Pa.s)	>35,000 cP
	Density	0.85-1.15 g/cm^3	0.85-1.15 g/cm^3
	pH	5.5-8	5.5 – 7.8
Biocompatibility		Meets ISO 10993-1:2018 requirements for irritation, sensitization, and cytotoxicity	Meets ISO 10993-1:2009 requirements for irritation, sensitization, and cytotoxicity
Utility		Single-Use (20ml pouch, sterile packet) Multi-Use (2.2OZ tube, non-sterile packet; 8.5OZ, 5000ml bottles, non-sterile packet)	Single-Use (20g sterile and non-sterile packets) Multi-Use (250g pouch)
Sterility (Method)		Sterile (Gamma); Non-Sterile	Sterile (Gamma); Non-Sterile
Environment of Use		Healthcare Facility	Healthcare Facility
Target Population		Adult and Pediatric	Adult and Pediatric
Labeling		Prescription Use	Prescription Use
Shelf Life		3 year	1 year

*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.

Summary of non-clinical and performance testing Bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according to, by FDA, recognized consensus standards ISO 10993-1, ISO 11137-1, ISO 11607-1. Results from testing performed confirms that the design requirement specification and user needs have been met. The subject device is confirmed to be safe and effective for the intended use.

Bench Testing

Test Item	Description	Test Results
Sound Velocity (Acoustic Velocity)	Measured at 35°C ,The Sound Velocity (Acoustic Velocity) shall be 1520 ~ 1620m/s	1569m/s ~1570m/s Pass
Acoustic Impedance	Measured at 35°C ,Acoustic Impedance shall be 1.5×10^6～1.7×10^6 Pa·s/m	1.593×10^6Pa·s/m ~1.597×10^6Pa·s/m Pass
Sound Attenuation	Measured at 35°C ,Sound Attenuation shall be ≦0.1dB/(cm·MHz)	0.042dB/(cm·MHz) -0.049 dB/(cm·MHz) Pass
Viscosity	Measured at 25°C, ≥4000cP(1000 Cp=1Pa.s)	8844 cP ~13720 cP Pass
Density	The density of the product shall be 0.85-1.15	1.021-1.022 Pass
pH	The pH value of the product should be 5.5~8.0	6.68~6.73 Pass
Sterility	The product should be sterile after being sterilized by confirmed gamma sterilization.	Pass
Microbiological Growth	TAMC≤100CFU/g TYMC≤100CFU/g	TAMC＜10CFU/g TYMC＜10CFU/g Pass
Appearance	Colorless or light transparent gel, no or only a few bubbles, non-soluble foreign bodies	Pass

Biocompatibility Testing

The biocompatibility evaluation for the proposed Ultrasound Gel was conducted in

accordance with the FDA Final Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" September 04, 2020, and International Standard ISO 10993-1:2018 "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** - ISO 10993-5:2009 (R) 2014 Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity
- **Irritation** - ISO 10993-23:2021—Biological evaluation of medical devices — Part 23: Tests for irritation
- **Sensitization** - ISO 10993-10:2021—Biological Evaluation of Medical Devices-Part 5: Tests for Irritation and Skin Sensitization
- **Acute Systemic Toxicity** -ISO 10993-11 : 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- **Pyrogen** -ISO 10993-11 : 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

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

Sterilization

Sterile Ultrasound Gel was validated for sterilization using gamma irradiation 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.

Packaging Validation and Shelf Life

Sterile and Non-Sterile Ultrasound Gels underwent packaging validation testing and accelerated aging testing per the below standards in order to support three years 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 F1980-22, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

VIII. CONCLUSION

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