September 19, 2024

Anhui Deepblue Medical Technology Co., Ltd.
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
CHINA

Re: K242167
Trade/Device Name: Sterile and Non-Sterile Ultrasonic Coupling Agent
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: MUI
Dated: July 24, 2024
Received: July 24, 2024

Dear Boyle Wang:

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.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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)*
K242167

Device Name
Sterile and Non-Sterile Ultrasonic Coupling Agent

Indications for Use *(Describe)*
Sterile and Non-Sterile Ultrasonic Coupling Agent 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.
The gels can be used during the procedures that involved adults and pediatrics in professional healthcare facility.

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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K242167

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

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Contact: Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date submitted: Jul.19,2024

2.0 Device Information

Trade name: Sterile and Non-Sterile Ultrasonic Coupling Agent
Common name: Diagnostic ultrasonic transducer
Classification name: Media, Coupling, Ultrasound
Production code: MUI
Regulation number: 21 CFR 892.1570
Classification: Class II
Panel: Radiology

3.0 Predicate Device Information

Manufacturer: HR Pharmaceuticals, Inc.
Trade/Device Name: EcoVue® Sterile and Non-Sterile Ultrasound Gels
510(k) number: K181363

4.0 Device Description

The subject device, Sterile and Non-Sterile Ultrasonic Coupling Agent, are non-irritating, non-sensitizing acoustic couplants intended for use as a scanning gel in medical diagnostic ultrasound procedures. The Ultrasonic Coupling Agent is an accessory used to couple sound waves between the patient and the medical imaging electronic transducers during diagnostic ultrasound procedures. The Ultrasonic Coupling Agent 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 Ultrasonic Coupling Agent is formulated to improve the acoustic transmission of sound waves to create the ultrasound image.

5.0 Indication for Use Statement

Sterile and Non-Sterile Ultrasonic Coupling Agent 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.
The gels can be used during the procedures that involved adults and pediatrics in professional healthcare facility.

6.0 Summary of Non-Clinical Testing

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.

6.1 Sterilization - Sterile Ultrasonic Coupling Agent have successfully been tested according to ISO 11137-1.
6.2 Packaging Validation and Shelf Life - Sterile and Non-Sterile Ultrasonic Coupling Agent underwent packaging validation testing and real aging testing per ISO 11607-1, ASTM F88/F88M-15,ASTM D3078 standards in order to support three years shelf life.
6.2 Biocompatibility testing - Sterile and Non-Sterile Ultrasonic Coupling Agent have successfully been tested for cytotoxicity, sensitization and intracutaneously irritation. The test results verify that the biocompatibility criteria given in ISO 10993-1 are fulfilled. Sterile and Non-Sterile Ultrasonic Coupling Agent are non- irritating, non-sensitizing acoustic couplants.
6.3 Performance testing – Bench The performance of Sterile and Non-Sterile Ultrasonic Coupling Agent has been verified. Tests as described in table 1 have been

completed.

Table 1: Performance testing summary – Bench

Test Item	Description	Test Results
Sound Velocity (Acoustic Velocity)	Measured at 35°C,The Sound Velocity (Acoustic Velocity) shall be 1520-1620m/s	1541.8m/s ~1551.7m/s Pass
Acoustic Impedance	Measured at 35°C ,Acoustic Impedance shall be 1.5×10^6～1.7×10^6 Pa·s/m	1.58×10^6Pa·s/m~ 1.59×10^6Pa·s/m Pass
Sound Attenuation	Measured at 35°C ,Sound Attenuation shall be ≦0.1dB/(cm·MHz)	0.04dB/(cm • MHz)~ 0.07dB/(cm • MHz) Pass
Viscosity	Measured at 25°C, the viscosity of the product should not be less than 15Pa·s.	42Pa·s~50 Pa·s Pass
Density	The density of the product shall be 987-1049kg/m^3	1024.5kg/m^3~1029.7kg/m^3 Pass
pH	The pH value of the product should be 5.5~8.0	6.62~6.86 Pass
Microbial Limit (Non-sterile Ultrasonic Coupling Agent)	The total number of aerobic bacteria shall not exceed 10^2cfu/g, and the total number of fungi and yeast shall not exceed 10^1cfu/g; Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans cannot be detected.	Pass
Sterility (Sterile Ultrasonic Coupling Agent))	The product should be sterile after being sterilized by confirmed gamma sterilization.	Pass
Appearance	1) The product shall generally be colorless or light colored transparent gel without insoluble foreign matters. 2) Under normal storage conditions, the product shall be free from stratification, mildew and odor.	Pass

7.0 Summary of Clinical Testing

No clinical study is included in this submission.

8.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device
510(k) No.	K242167	K181363
Product Code	MUI	MUI
Regulation No.	21 CFR 892.1570	21 CFR 892.1570
Class	II	II
Intended Use/Indication for Use	Ultrasonic Coupling Agent 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. The gels can be used during the procedures that involved adults and pediatrics in professional healthcare facility.	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 polymer gel (sterile and non-sterile)	Water-based gel (sterile and non-sterile)
Model	Tubes 10g,20g, 30g (Sterile) Bottles 50g,100g, 250g,1000g, 2500g,5000g(non-sterile)	20g individual packets (both sterile and non-sterile) 250g pouch (non-sterile)
Sterile	Both in Gamma sterilization and non-sterile , SAL 10^{-6}	Both in Gamma sterilization and non-sterile
Shelf Life	3 years	1 years
Appearance	The product shall be colorless or light-colored transparent gel without insoluble foreign matters	Clear to Hazy Color; free from foreign matter
Sound Velocity (Acoustic Velocity)	1520-1620m/s	1398-1750 m/s
Acoustic Impedance	$1.5\times10^6\sim1.7\times10^6$ Pa·s/m	1.40×10^6-1.80×10^6 Pa·s/m
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	≥15Pa·s	>35,000 cP

Density	987-1049kg/m^3	850-1150 kg/cm^3
pH	5.5~8.0	5.5 – 7.8
Biocompatibility	Conform with ISO 10993 standards	Conform with ISO 10993 standards

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the following:

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

Physical and Chemical Properties of the subject device are a little different with those of the predicate device, but all the required values are within those of predicate device. Additionally, side-by-side testing confirmed that the subject devices are substantially equivalent to the predicate devices.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device in K181363 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.