August 29, 2022

Hony Medical Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
CHINA

Re: K221999
Trade/Device Name: Ultrasound Transmission Gels
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: MUI
Dated: May 25, 2022
Received: July 7, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For

Michael D. O'Hara, Ph.D.
Deputy Director
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)*
K221999

Device Name
Ultrasound Transmission Gels

Indications for Use *(Describe)*
Ultrasound Transmission 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.
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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# 510(k) Summary

# K221999

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

Name: Hony Medical Co., Ltd.
Address: No.12,9Road,Changlong Ind.Zone,Taishan City,Guangdong, China 529222
Tel: +86 15916327827
Contact: Zhu Huina

**Designated Submission Correspondent**

Contact: Mr. Boyle Wang
Name: Shanghai Truthful Information Technology Co., Ltd.
Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

Date submitted: Aug.10,2022

## 2.0 Device Information

Trade name: Ultrasound Transmission Gels
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 Ultrasound Transmission Gels, which shall be colorless or light-colored transparent , 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.
The Ultrasound Transmission Gels are composed of purified water, glycerin, polyethylene glycol, carbomer, sodium hydroxide and phenoxyethanol. It 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 subject device is available in the below sizes: 5g/bag，10g/bag，15g/bag, 16g/bag, 20g/bag, 22g/bag, 25g/bag, individual, single-use packet.

As the device is single use device, which is individually packaged sterile devices. The packaging is compatible with the product's Gamma sterilization method. The sterilization validation confirms the packaging is qualified bacterial film to maintain the sterilization condition of the device.

## 5.0 Indication for Use Statement

Ultrasound Transmission 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.
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 and shelf life - Ultrasound Transmission Gels are delivered sterile and have successfully been tested according to 11137-1; the packaging after accelerated

aging for terminally sterilized devices has been verified per ISO 11607- 1. The label shelf life is 3 years.

6.2 Biocompatibility testing - Ultrasound Transmission Gels have successfully been tested for cytotoxicity, sensitization, intracutaneously irritation, and material medicated pyrogenicity Testing. The test results verify that the biocompatibility criteria given in ISO 10993-1 are fulfilled. Ultrasound Transmission Gels are non-toxic and biocompatible.

6.3 Performance testing – Bench The performance of Ultrasound Transmission Gels 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 | 1538.4m/s ~1538.4m/s<br>Pass |
| Acoustic Impedance | Measured at 35°C ,Acoustic Impedance shall be $1.5\times10^{6}$～$1.7\times10^{6}$ Pa·s/m | 1.56×106Pa·s/m ~1.63×106Pa·s/m<br>Pass |
| Sound Attenuation | Measured at 35°C ,Sound Attenuation shall be ≦0.1dB/(cm·MHz) | 0.01dB/(cm • MHz)<br>Pass |
| Viscosity | Measured at 25°C, the viscosity of the product should not be less than 15Pa·s. | 100Pa·s~103Pa·s<br>Pass |
| Density | The density of the product shall be 987-1049kg/$m^3$ | 1028.61kg/$m^3$~1033.39kg/$m^3$<br>Pass |
| pH | The pH value of the product should be 5.5~8.0 | 6.76~6.83<br>Pass |
| Antimicrobial Effectiveness | Bacteria: Not less than a 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days Yeast and Molds: No increase from the initial calculated count at 14 and 28 days | Pass |
| Sterility | The product should be sterile after being sterilized by confirmed gamma sterilization. | Pass |
| Appearance | The product is colorless or light-colored transparent gel without insoluble foreign matter. Under normal storage conditions of the product, there will be no delamination, 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. | Pending | K181363 |
| Product Code | MUI | MUI |
| Regulation No. | 21 CFR 892.1570 | 21 CFR 892.1570 |
| Class | II | II |
| Intended Use/Indication for Use | Ultrasound Transmission 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.<br>The gels are intended for use in all diagnostic ultrasound procedures which require coupling gel or fluid.<br>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.<br>The gels are intended for use in all diagnostic ultrasound procedures which require coupling gel or fluid. |
| Patient-contacting material | Purified water, glycerin, polyethylene glycol, carbomer, sodium hydroxide and phenoxyethanol. | Water-based gel<br>(sterile and non-sterile) |
| Model | 5g/bag ， 10g/bag ， 15g/bag, 16g/bag, 20g/bag, 22g/bag, 25g/bag | 20g individual packets (both sterile and non-sterile)<br>250g pouch (non-sterile) |
| Sterile | Gamma sterilization, SAL 10-6 | Both in Gamma sterilization and non-sterile |
| Shelf Life | 3 years | 1 years |
| Appearance | The product is colorless or light-colored transparent gel without insoluble foreign matter. | Clear to Hazy Color; free from foreign matter |
| Sound Velocity (Acoustic Velocity) | 1520-1620m/s | 1398-1750 m/s |

| | | |
|---|---|---|
| Acoustic Impedance | $1.5\times10^6$～$1.7\times10^6$ Pa·s/m | $1.40\times10^6$-$1.80\times10^6$ Pa·s/m |
| Sound Attenuation | ≦0.1dB/(cm·MHz) | 0.32-0.95 dB/cm at 5 MHz<br>0.65-1.10 dB/cm at 7.5 MHz<br>0.85-1.55 dB/cm at 10 MHz |
| Viscosity | ≥15Pa·s（15,000 cP） | >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 ISO10993-1 (ISO10993-5, ISO10993-10, ISO10993-11) | 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 indications for use
- Similar material types that meet ISO 10993 biocompatibility requirements
- Same sterilization methods
- Same fundamental technology/principal of operation/user interface

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.

The subject device is just provided in sterile condition while the predicate device is provided both in sterile and non-sterile condition, there is no significant risk raised by the difference.

## 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.