June 17, 2026

Foshan Pingchuang Medical Technology Co., Ltd.
% Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518000
CHINA

Re: K253255
Trade/Device Name: Non-Sterile Ultrasound Gel
Sterile Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: MUI
Dated: September 29, 2025
Received: September 29, 2025

Dear Grace Liu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

MARJAN NABILI -S for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253255

Please provide the device trade name(s).

Non-Sterile Ultrasound Gel
Sterile Ultrasound Gel

Please provide your Indications for Use below.

For Non-Sterile Ultrasound Gel:
Non-Sterile Ultrasound Gel is intended to be used on intact skin as a non-sterile transmission media for coupling sound waves between a patient and the ultrasound transducer during non-invasive diagnostic ultrasound imaging procedures.

For Sterile Ultrasound Gel:
Sterile Ultrasound Gel is intended to be used on intact skin as a sterile transmission media for coupling sound waves between a patient and the ultrasound transducer during non-invasive diagnostic ultrasound imaging procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary - K253255

1. Contact Details

1.1 Applicant information

Applicant Name	Foshan Pingchuang Medical Technology Co., Ltd.
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Contact person	Anthony Huang
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Date Prepared	2026-06-18

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District Shenzhen, Guangdong 518000 China
Phone No.	+86-755-86069197
Contact person	Grace Liu
Contact person's e-mail	grace@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Non-Sterile Ultrasound Gel Sterile Ultrasound Gel
Classification	II
Classification name	Diagnostic ultrasonic transducer
Product code	MUI
Regulation No.	21 CFR 892.1570

3. Legally Marketed Predicate Device

Trade Name	Ultra/Phonic® Scanning Gel
Manufacturer	Pharmaceutical Innovations, Inc.
510(k) Number	K163026
Product Code	MUI
Device Class	II
Regulation No.	21 CFR 892.1570

The predicate device has not been subject to any design-related recall.

4. Legally marketed reference device

Trade Name	Sterile and Non-Sterile Ultrasonic Coupling Agent
Manufacturer	Anhui Deepblue Medical Technology Co., Ltd.
510(k) Number	K242167
Product Code	MUI
Device Class	II
Regulation No.	21 CFR 892.1570

The reference device has not been subject to any design-related recall.

5. Device Description

Non-Sterile Ultrasonic Gel and Sterile Ultrasonic Gel are water-soluble, clear gel, and they are a type of conductive medium used in ultrasound diagnostic imaging procedures.

When the ultrasound gel is placed between the intact skin of patients and the medical electronic transducers, it eliminates air at the contact surface while providing coupling, so that it provides an acoustic pathway between the intact skin of patients and the medical electronic transducers. This pathway allows the transducer to send sound waves which enter the body, and to receive echoes from tissues and structures .

Non-Sterile Ultrasonic Gel is provided non-sterile, and it is available in several specifications: 60g/bottle, 80g/bottle, 100g/bottle, 150g/bottle and 250g/bottle. Sterile Ultrasonic Gel is a single-use device, provided sterile, and it is available in several specifications: 10g/bag, 12g/bag, 15g/bag, 20g/bag and 30g/bag.

The shelf life of both Non-Sterile Ultrasonic Gel and Sterile Ultrasonic Ge is 3 years.

6. Intended Use/Indication for Use

For Non-Sterile Ultrasound Gel:

Non-Sterile Ultrasound Gel is intended to be used on intact skin as a non-sterile transmission media for coupling sound waves between a patient and the ultrasound transducer during non-invasive diagnostic ultrasound imaging procedures.

For Sterile Ultrasound Gel:

Sterile Ultrasound Gel is intended to be used on intact skin as a sterile transmission media for coupling sound waves between a patient and the ultrasound transducer during non-invasive diagnostic ultrasound imaging procedures.

7. Substantial Equivalence Comparison

Comparison Item	Proposed Device (K253255)	Predicate Device (K163026)	Reference Device (K242167)	Comment
Manufacturer	Foshan Pingchuang Medical Technology Co., Ltd.	Pharmaceutical Innovations, Inc.	Anhui Deepblue Medical Technology Co., Ltd.	/
Product Name	Non-Sterile Ultrasound Gel Sterile Ultrasound Gel	Ultra/Phonic® Scanning Gel	Sterile and Non-Sterile Ultrasonic Coupling Agent	/
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570	Same
Product code	MUI	MUI	MUI	Same
Classification	Class II	Class II	Class II	Same
Prescription Use	Yes	Yes	Yes	Same
Intended Use / Indications for Use	For Non-Sterile Ultrasound Gel: Non-Sterile Ultrasound Gel is intended to be used on intact skin as a non-sterile transmission media for coupling sound waves between a patient and the ultrasound transducer during non-invasive diagnostic ultrasound imaging procedures. For Sterile Ultrasound Gel: Sterile Ultrasound Gel is intended to be used on intact skin as a sterile transmission media for coupling	Ultra/Phonic® Scanning Gel is intended for general use as a non-sterile transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin or on the transducer prior to initiating an ultrasound examination. The product is indicated for prescription use only.	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	Equivalent to the predicate device.

		sound waves between a patient and the ultrasound transducer during non-invasive diagnostic ultrasound imaging procedures.		pediatrics in professional healthcare facility.	
Target patients		Adults and Pediatrics	Adults and Pediatrics	Adults and Pediatrics	Same
Environment of Use		Healthcare facility	Healthcare facility	Healthcare facility	Same
Usage		Non-Sterile: multiple use bottles Sterile: single use packages	Multiple use bottles	Non-Sterile: multiple use bottles Sterile: single use packages	Non-Sterile is the same with the predicate device; Non-sterile and Sterile are the same with the reference device.
Patient-contacting material		Water-based polymer gel	Water-based polymer gel	Water-based polymer gel	Equivalent
Performances	Appearance	The product is colorless or light-colored transparent gel without insoluble foreign matter.	Green coloring, high clarity	The product shall be colorless or light-colored transparent gel without insoluble foreign matters.	Equivalent
	Density	0.85-1.15g/ml	1.035g/ml	987-1049 kg/m^3	Different
	pH	5.5-7.5	6.25±0.25	5.0-8.0	
	Viscosity	≥15 Pa·s	200,000±100,000 cps	≥15 Pa·s	Same with the reference device
	Acoustic Velocity	1520-1620 m/s at 35℃	1590 m/s at 22.5℃	1520-1620 m/s at 35℃	
	Acoustic Impedance	1.5×10^6-1.7×10^6 Pa·s/m at 35℃	1.65×10^6 Pa·s/m at 22.5℃	1.5×10^6-1.7×10^6 Pa·s/m at 35℃	
	Acoustic	≤0.1 dB/(cm·MHz) at 35℃	$0.06+0.01116f^{1.3706}$ dB/(cm·MHz)	≤0.1 dB/(cm·MHz) at 35℃	

	Attenuation				
Biocompatibility		Conform with ISO 10993 series standards (cytotoxicity, skin sensitization, and skin irritation)	Conform with ISO 10993 series standards (cytotoxicity, skin sensitization, and skin irritation)	Conform with ISO 10993 series standards (cytotoxicity, skin sensitization, and skin irritation)	Same
Sterility		Non-Sterile: non-sterile Sterile: Gamma radiation, SAL 10^{-6}	Non-sterile: non-sterile	Non-sterile: non-sterile Sterile: Gamma radiation, SAL 10^{-6}	Non-Sterile is the same with the predicate device; Non-sterile and Sterile are the same with the reference device.

In conclusion, the proposed device has the similar indication for use to the predicate device (K163026), and also has similar technical characteristics to the predicate device (K163026) and the reference device (K242167). The differences don't raise any additional questions for safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device (K163026).

8. Summary of Non-clinical Testing

Non-clinical tests were conducted to demonstrate the safety and effectiveness of the proposed device and the substantial equivalence to the predicate device. The following tests were conducted.

Performance testing:

The following performance tests have been performed on Non-Sterile Ultrasonic Gel and Sterile Ultrasonic Gel, according to the technical specifications, and the results demonstrate the subject device can meet the technical specifications.

- Physical and chemical performances (including Appearance, pH, Viscosity and Relative density)
- Acoustic performances (including Acoustic velocity, Acoustic impedance and Acoustic attenuation)
- Microbiological performances

  - Microbial limits and Antimicrobial effectiveness (only for Non-Sterile Ultrasonic Gel)

  - Sterility (only for Sterile Ultrasonic Gel)

Biocompatibility:

The following biocompatibility tests have been performed on Non-Sterile Ultrasonic Gel and Sterile Ultrasonic Gel, according to *FDA guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on Sep. 8, 2023*, and the test results showed that the proposed device has no biocompatibility issues.

- Cytotoxicity as per ISO 10993-5:2009
- Skin Irritation as per ISO 10993-23:2021
- Skin Sensitization as per ISO 10993-10:2021

Sterilization:

For Sterile Ultrasonic Gel, a Sterility Assurance Level (SAL) of 10^{-6} has been validated in accordance with the requirements of ISO 11137-1:2006, ISO 11137-2:2013 and 11137-3:2017.

Shelf Life:

Real-time aging has been performed on Non-Sterile Ultrasonic Gel and Sterile Ultrasonic Gel, to assure the shelf-life of 3 years.

Simulated Transportation Testing:

The simulated transportation testing has been conducted on Non-Sterile Ultrasonic Gel and Sterile Ultrasonic Gel according to ASTM D4169-23.

9. Clinical Testing

This 510(k) submission does not utilize clinical study for establishing substantial equivalence, therefore this section

does not apply.

10. Conclusions

A comparison of the intended use, design specifications, and results of non-clinical testing between the proposed device and the legally marketed predicate device (K163026) raised no new questions of safety and effectiveness and show that they are Substantially Equivalent (SE).