July 3, 2024

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

Re: K241615
Trade/Device Name: Transducer Probe Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: June 5, 2024
Received: June 5, 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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241615

Device Name

Transducer Probe Cover

Indications for Use *(Describe)*

Transducer Probe Cover placed over diagnostic ultrasound transducer/ probe scan head instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer. The cover also provides a means for maintenance of a sterile field. Transducer Probe Cover are furnished sterile; single use patient/procedure, disposable.

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.

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510(k) Summary

K241615

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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Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Email: Info@truthful.com.cn

Date of Preparation: Jun.27,2024

2.0 Device Information

Trade name: Transducer Probe Cover
Common name: Ultrasonic Diagnostic Transducer Probe Cover
Classification name: Transducer, Ultrasonic, Diagnostic.
Model(s): Various Dimension
Production code: ITX
Regulation number: 21 CFR 892.1570
Classification: Class II
Panel: Radiology

3.0 Predicate and Reference Device Information

Predicate#

Manufacturer: Hony Medical Co., Ltd.
Trade Device: Transducer Probe Cover

510(k) number: K221278

Reference#

Manufacturer: CIVCO MEDICAL INSTRUMENTS CO., INC.
Trade Device: GENERAL PURPOSE TRANDUCER COVER
510(k) number: K970513

4.0 Device Description

The subject device is composed of transparent thin-walled polyurethane sleeve, rubber ring and (or) tape strip. A conventional 0.05mm thin, 49 GSM (Grams per Square Meter), transparent high strength polyurethane film tube shape, in various dimensions with heat sealed distal end to be applied over a transducer probe to provide a Transducer Cover that can be used to minimize contamination between patient and ultrasound probe during ultrasound scanning procedures for body surface, endocavity and intra-operative diagnostic ultrasound. This may help with easier cleaning and disinfection of the probe.

Ultrasound imaging is not impaired by use of the cover as it is intended. Adequate coupling between the cover and the transducer is required. The Transducer Probe Cover is utilized by applying sterile transmission, coupling, or lubricating gel onto the transducer face or into closed end of cover, inserting ultrasound transducer into closed end of cover and unrolling cover over length of the transducer as desired, and securing open end of cover with bands as necessary the removal process is accomplished by pulling the cover off the transducer in a reverse method from the application.

The subject device is furnished in sterile condition, for single use patient/procedure use, disposable.

As the device is single use device, which is individually packaged sterile devices. The packaging is compatible with the product's EO 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

Transducer Probe Cover placed over diagnostic ultrasound transducer/ probe scan head instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer. The cover also provides a means for maintenance of a sterile field.

Transducer Probe Cover are furnished sterile; single use patient/procedure, disposable.

6.0 Summary of Non-Clinical Testing

In this current submission, just expand the intended use scope of the subject device. As there were no materials, structure, dimensions or performance changes made to the subject device when compared to the primary predicate device, no additional non-clinical testing was considered necessary to support the substantial equivalence**.**

Performance Bench Testing

As there are no any technological characteristics changes as part of this submission from the previous clearance, no performance bench testing was included as part of this submission.

There are no differences between the predicate Transducer Probe Cover and the proposed Transducer Probe Cover that could affect the shelf life or sterility; therefore, sterilization and shelf-life evaluations were not required.

Biocompatibility Testing

The proposed Transducer Probe Cover does not introduce any new direct or indirect patient contacting materials, as compared to the previous clearance predicate Transducer Probe Cover.

Since the subject device expand the indication for use scope, it can be used in endocavity, and intra-operative diagnostic ultrasound, additionally biocompatibility evaluation Items including Thrombogenicity and Complement Activation Testing

Per ISO 10993-4 were performed due to the contact level of tissue. And the biocompatibility test results reviewed by the FDA for the predicate Transducer Probe Cover (reference K221278) also valid, can be support the proposed Transducer Probe Cover.

7.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device	Reference Device	Conclusion
510(k) No.	K241615	K221278	K970513	--
Product Code	ITX	ITX	ITX	Same
Regulation No.	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570	Same
Class	II	II	II	Same
Intended Use/Indication for Use	Transducer Probe Cover placed over diagnostic ultrasound transducer/ probe scan head instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer. The cover also provides a means for maintenance of a sterile field. Transducer Probe Cover are furnished sterile; single use patient/procedure, disposable.	Transducer Probe Cover placed over diagnostic ultrasound transducer/ probe scan head instruments. The cover allows use of the transducer in scanning and needle guided procedures for external intact skin diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer. The cover also provides a means for maintenance of a sterile field. Transducer Probe Cover are furnished sterile; single use patient/procedure, disposable.	Protective cover or sheath placed over diagnostic ultrasound transducer / probe scan head instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids , and particulate material to the patient and healthcare worker during reuse of the transducer (both sterile and non-sterile covers) . The cover also provides a means for maintenance of a sterile field (sterile covers only) . CIVCO Poly Uitrasound Transducer	Compare to the predicate device, the subject device expanded the scope of the indication for use. The subject device additionally can be used for endocavity, and intra-operative diagnostic ultrasound. Thrombogenicity and Complement Activation Testing were performed due to the contact level of tissue.

			Covers are furnished sterile & non-sterile single use patient / procedure, disposable.	
Materials & Construction	Polyurethane, tubular, sealed	Polyurethane, tubular, sealed	Polyurethane and polyethylene extruded thermoplastic film, in one-piece, open on one end, closed on other end.	Same
Model	Various Size	Various Size	Various Size	Same
Microbial Barrier	Meets requirements of ASTM F1671-13 for prevention of blood-borne pathogens	Meets requirements of ASTM F1671-13 for prevention of blood-borne pathogens	Not Publicly Available	Same
Acoustic Performance	Acoustic Impedance: 1.60 x 10^6 Pa s/m	Acoustic Impedance: 1.60 x 10^6 Pa s/m	Not Publicly Available	Same
	Acoustic Velocity: 1594 m/s	Acoustic Velocity: 1594 m/s	Not Publicly Available	
	Acoustic Attenuation: 0.01dB/(cm·MHZ）	Acoustic Attenuation: 0.01dB/(cm·MHZ）	Not Publicly Available	
Sterile	EO sterilization, SAL 10^{-6}	EO sterilization, SAL 10^{-6}	Both in EO sterilization and non-sterile	Same
Disposable, Single Use Only	Yes	Yes	Yes	Same
Shelf Life	3 years	3 years	Not Publicly Available	Same
Biocompatibility	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO 10993 standards	Thrombogenicity , Complement Activation Testing and Platelet Activation Test per ISO

				10993-4 were performed due to the contact level of tissue.

Except the expand the applicable scope of indication for use for the subject device, there is no any changes made on the technological characteristics of the subject device are identical to those of predicate device. The materials, dimensions, sterilization methods, processing and manufacturing are no any changes were made to the subject device.

The subject device is substantially equivalent to the predicate devices with respect to technological characteristics, and performance characteristics. The differences between the applicable scope of the proposed and predicate devices do not alter the substantially equivalent since additional biocompatibility testing evaluation has been performed.

8.0 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 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.