January 11, 2023

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

Re: K221278
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: December 7, 2022
Received: December 15, 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,

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)*
K221278

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 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K221278

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 of Preparation: Jan.11,2023

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: CIVCO MEDICAL INSTRUMENTS CO., INC.
Trade Device: GENERAL PURPOSE TRANDUCER COVER

510(k) number: K970513

Reference#

Manufacturer: CIVCO MEDICAL INSTRUMENTS CO., INC.
Trade Device: CIV-Clear cover
510(k) number: K211270

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 external intact skin. 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 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.

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 10993-7, 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 - Transducer Probe Cover is delivered sterile and have successfully been tested according to ISO 11607- 1. The label shelf life is 3 years.
6.2 Biocompatibility testing - Transducer Probe Cover has successfully been tested for cytotoxicity, sensitization, intracutaneously irritation, acute systemic toxicity, material medicated pyrogenicity and Hemolysis Testing. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. Transducer Probe Cover is non-toxic and biocompatible.
6.3 Performance testing – Bench The performance of Transducer Probe Cover has been verified. Tests as described in table 1 have been completed.

Table 1: Performance testing summary – Bench

Test Item	Acceptance Criteria	Result Summary
Viral Penetration	To validate the ability to withstand viral penetration per ASTM F1671-13.	Meets requirements of ASTM F1671 for prevention of blood-borne pathogens, and the material has been tested and proven to be a viral barrier for microbes 25 nanometers and larger in size.
Tensile	The maximum tensile force for longitudinal breaking of the membrane of the Transducer Probe Cover shall be no less than 20N, the maximum tensile force for transverse breaking shall not be less than 10N, and the elongation at break of the membrane of the disposable ultrasonic inspection sheath shall not be less than 100%.	Meets requirements of ISO 527-3:1995. Tensile strength: 37.41N/25mm, longitudinal tensile strength: 39.25N/25mm, elongation at break: 517.51%
Tear resistance	Under the specified conditions, test the tearing strength of the disposable ultrasonic inspection sheath is not less than 5N	Meets requirements of ISO 9073-4-2021 Longitudinal crack resistance: 16.64N Lateral crack resistance: 17.64N
Water resistance	To determine the resistance of the materials to the penetration of water by impact. The time that can withstand 500mm hydrostatic pressure should not be less than 300s.	Meet the requirements
Acoustic properties	Sound Attenuation: Measured at 35°C ,Sound	Meet the requirements:

	Attenuation shall be ≦0.1dB/(cm·MHz); Acoustic Impedance: Measured at 35°C ,Acoustic Impedance shall be 1.5×106～1.7×106 Pa·s/m Sound Velocity: Measured at 35°C, the Sound Velocity (Acoustic Velocity) shall be 1520-1620m/s.	Acoustic Velocity: 1594.4 m/s; Acoustic Attenuation: 0.01dB/(cm·MHZ） Acoustic Impedance:1.60 Pa·s/m The Transducer Probe Cover does not affect the acoustic properties of the ultrasound device.
Force at Break and Tear Resistance Properties	To demonstrate material breaking force property and tear resistance property per ISO 527-3:2018	Meets requirements of ISO 527-3:2018: Force at break:28.85 N/25mm; Tear resistance:515%.
Water Leakage	Watertightness Test for Detection of Holes. The subject probe cover shall be free of pinhole	No Water Leakage
Airburst pressure and Volume	To demonstrate the mechanical strength and durability. The Airburst Pressure shall not be less than 1.0 kpa and the volume shall be not less than 28 dm^3 for cover with a mid-body width greater than or equal to 65,0 mm and less than 75,0 mm	Meets requirements of ISO 4074:2014 Airburst Pressure:3.08 kpa Volume:80.66 dm^3
Ultrasound imaging effect	Ultrasound imaging is not impaired by use of the cover as it is intended	Meets requirements The image is clear.

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	Reference Device	Conclusion
510(k) No.	K221278	K970513	K211270	--
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 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	The cover is intended as a microbial barrier between the patient and medical imaging equipment. The transducer covers are used for adult of all body sizes in sterile and non-sterile fields and for the following applications. • Abdominal - Diagnostic imaging and minimally invasive puncture procedures. • Small Parts - Diagnostic imaging and minimally invasive puncture procedures. • Regional Anesthesia - Minimally invasive puncture procedures. • Vascular Access - Vessel identification and catheter	Similar with the predicate device

		Covers are furnished sterile & non-sterile single use patient / procedure, disposable.	placement. • Surgical - Diagnostic imaging and puncture procedures. •Transesophageal - Diagnostic imaging and monitoring of heart chamber, valves and vessels. • Transrectal – Diagnostic imaging and minimally invasive puncture procedures. • Transvaginal – Diagnostic imaging and minimally invasive puncture procedures	
Materials & Construction	Polyurethane, tubular, sealed	Polyurethane and polyethylene extruded thermoplastic film, in one-piece, open on one end, closed on other end.	Ethyl Methyl Acrylate (EMA) and Polyethylene blend	All the device have passed the biocompatibility evaluation
Model	Various Size	Various Size	Various Size	Same
Microbial Barrier	Meets requirements of ASTM F1671-13 for prevention of blood-borne pathogens	Not Publicly Available	Meets requirements of ASTM F1671-13 for prevention of blood-borne pathogens	Same with the Reference device.
Acoustic Performance	Acoustic Impedance: 1.60 x 10^6 Pa s/m	Not Publicly Available	1.54 x 10^6 g/ Pa s/m	The subject transducer probe cover has negligible effect on the transmission of ultrasound signal and the transducer probe
	Acoustic Velocity: 1594 m/s	Not Publicly Available	1630 m/s	
	Acoustic Attenuation: 0.01dB/(cm·MHZ）	Not Publicly Available	Not Publicly Available	

				cover does not degrade signal or image.
Sterile	EO sterilization, SAL 10^{-6}	Both in EO sterilization and non-sterile	Both in EO sterilization and non-sterile	Same
Disposable, Single Use Only	Yes	Yes	Yes	Same
Shelf Life	3 years	Not Publicly Available	3 years	Same with the Reference Device
Biocompatibility	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO 10993 standards	Conform with ISO10993-1 (ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11)	Same

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
- Similar material types that meet ISO 10993 biocompatibility requirements
- Same sterilization methods
- Same fundamental technology/principal of operation/user interface

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