August 30, 2024

Vitrolife Sweden AB
Lin Huldeberg
Regulatory Affairs Manager
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SWEDEN

Re: K241662
Trade/Device Name: Ultrasound Transducer Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX
Dated: June 10, 2024
Received: June 10, 2024

Dear Lin Huldeberg:

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
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241662

Device Name
Ultrasound Transducer Cover

Indications for Use *(Describe)*
The device is intended to cover an ultrasound transducer and to act as a microbial barrier between the patient and the transducer during transvaginal procedures within assisted reproductive technology or gynecology, for clinical and hospital use by healthcare professionals in adult patients undergoing these procedures.

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 – K241662

Date prepared: August 30, 2024

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1 Device Information

Trade Name:	Ultrasound Transducer Cover
Common name:	Ultrasound Transducer Cover
Regulation number:	21 CFR 892.1570
Regulation name:	Diagnostic ultrasonic transducer
Product code:	ITX (Class 2) - Transducer, Ultrasonic, Diagnostic
Class:	II

1.1 Predicate Device:

CIV-Clear cover, Manufactured by CIVCO Medical Instruments Co., Inc. – K211270

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

1.2 Reference Device:

Transducer Probe Cover, Manufactured by Hony Medical Co., Ltd. – K221278

2 Device description

The Ultrasound Transducer Cover is an elastic cover made of thermoplastic polyurethane (TPU), which is placed over the ultrasound transducer during ultrasound guided procedures within assisted reproductive technology or gynecology. The Ultrasound Transducer Cover is provided sterile (ethylene oxide), for single use, and used with an ultrasound transducer probe to facilitate ultrasound scans.

The Ultrasound Transducer Cover is available in various sizes with different widths of the cover. This is to allow for use with various sizes of ultrasound transducer probe.

2.1 Intended use / Indications for Use

The device is intended to cover an ultrasound transducer and to act as a microbial barrier between the patient and the transducer during transvaginal procedures within assisted reproductive technology or gynecology, for clinical and hospital use by healthcare professionals in adult patients undergoing these procedures.

3 Summary of Non-clinical Testing

The following tests have been conducted in order to verify the safety and effectiveness of the device:

- Functional testing
  - Ultrasound imaging effect – No negative effect on ultrasound visibility
  - Acoustic impedance, Acoustic Velocity & Acoustic Attenuation – Ultrasound Transducer Cover does not affect the acoustic properties of the ultrasound device
  - Elongation properties – Device does not break when pulled onto the transducer probe
  - Leakage – Device does not leak

- Biocompatibility– evaluated/tested against ISO 10993-1 and FDA Biocompatibility Guidance endpoints relevant for a limited contact surface medical device in contact with “breached or compromised surface”:
  - Physical and /or chemical characterization
  - Cytotoxicity
  - Skin Sensitization
  - Irritation (skin/vaginal)/Intracutaneous reactivity
  - Material mediated pyrogenicity
  - Acute systemic toxicity
  - Reproductive and developmental toxicity

- Safety testing
  - Endotoxin testing – Device is nontoxic with regards to endotoxins (< 20 EU/device)
  - Viral penetration – No viral penetration, tested according to ASTM F1671

- Package validation and testing – The sterility is maintained by ensuring that the packaging is in conformance with ISO 11607-1 and ISO 11607-2, and that the packaging methods are validated accordingly. Sterile barrier testing includes:
  - Seal strength (ASTM F88 / F88M)
  - Dye penetration (ASTM F1929)
  - Opening characteristics of pouch (EN 868-5)
  - Visual inspection of seals (ASTM F1886 / F1886M)
  - Seal width

- Shelf-Life testing
  - Aging tests have been performed, concluding that the device and packaging upholds its functionality over the three-year shelf-life

- Transport testing
  - Transport testing of package according to ASTM D4169

- Ethylene Oxide (EO) Sterilization Validation and Residual testing
  - Sterilization validation according to ISO 11135
  - EO residual levels do not exceed the limits per ISO 10993-7 for a limited exposure category device

4 Clinical Testing

Not applicable.

5 Comparison of Subject and Predicate Device Intended Use and Technological Characteristics

Table 1. Predicate comparison table to outline differences and similarities between the subject, predicate and reference devices

Description	**Subject Device – Ultrasound Transducer Cover (K241662)**	**Predicate Device – CIV-Clear cover (CIVCO) (K211270)**	**Reference Device – Transducer Probe Cover (Hony) (K221278)**	**Differences**
Product code	ITX	ITX	ITX	Same
Regulation	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570	Same
Class	II	II	II	Same
Intended use / Indications for use	The device is intended to cover an ultrasound transducer and to act as a microbial barrier between the patient and the transducer during transvaginal procedures within assisted reproductive technology or gynecology, for clinical and hospital use by healthcare professionals in adult patients undergoing these procedures.	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 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 When conducting an ultrasound procedure, place an appropriate amount of gel inside cover and/or on transducer face.	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.	Although not phrased the same, the Transvaginal use of the Predicate device is the same as for the Subject device.

Size(s)		Various sizes: - 60X610 mm - 80x610 mm - 100x610 mm	Various sizes (details unknown)	Various sizes: - 60X610 mm - 80x610 mm - 100x610 mm	**Different**: The size and shape of the Predicate device is not known; however, any differences does not raise different questions of safety and effectiveness (S&E)
Material		Thermoplastic Polyurethane	Ethyl Methyl Acrylate (EMA) and Polyethylene blend	Thermoplastic Polyurethane	**Different**: The subject and predicate device materials are not the same. Differences in materials does not raise different questions of S&E, since both devices are considered biologically safe. Same material as the reference device.
Biocompatibility		Cytotoxicity (ISO 10993-5) Irritation (ISO 10993-10) Sensitization (ISO 10993-10) Intradermal reactivity (ISO 10993-10) Acute systemic toxicity (ISO 10993-11) Vaginal Irritation (ISO 10993-10) Material-mediated Pyrogenicity (ISO 10993-11)	Cytotoxicity (ISO 10993-5) Irritation (ISO 10993-10) Sensitization (ISO 10993-10) Acute Systemic Toxicity (ISO 10993-11) Material Mediated Pyrogenicity (ISO 10993-11)	Cytotoxicity (ISO 10993-5) Irritation (ISO 10993-10) Sensitization (ISO 10993-10) Acute Systemic Toxicity (ISO 10993-11) Material Mediated Pyrogenicity (ISO 10993-11) Hemolysis (ISO 10993-4	Same, plus more, compared to the Predicate device
Sterilization		Ethylene Oxide	Ethylene Oxide (Offered in sterile and non-sterile configurations)	Ethylene Oxide	Same
Shelf-life		3 years	3 years	3 years	Same
Single use		Yes	Yes	Yes	Same
Microbial barrier		Meets requirements of ASTM F1671-22 for prevention of blood-borne pathogens	Meets requirements of ASTM F1671-13 for prevention of blood-borne pathogens	Meets requirements of ASTM F1671-13 for prevention of blood-borne pathogens	Same
Acoustic Performance	Acoustic Impedance	1.60 x 10^6 Pa s/m	1.54 ± 0.13 x 10^5 g/(cm^2 sec)	1.60 x 10^6 Pa s/m	Same
	Acoustic Velocity	1594 m/s	1630 m/s	1594 m/s	Same
	Acoustic Attenuation	0.01dB/(cm·MHZ)	Unknown	0.01dB/(cm·MHZ)	Same

6 Conclusions

As concluded in the comparison above, the Subject device has the same intended use/indications for use as the Predicate device, and their differences in technological characteristic does not raise different questions of safety and effectiveness. Therefore, the Ultrasound Transducer Cover is concluded substantially equivalent to the legally marketed Predicate device.