CIVCO Medical Instruments Co., Inc.
% Jim Leong
Regulatory Affairs Manager
102 First Street South
KALONA IA 52247

September 13 , 2021

Re: K211270
Trade/Device Name: CIV-Clear cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: July 20, 2021
Received: July 28, 2021

Dear Jim Leong:

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 and Part 809); 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K211270

Device Name
CIV-Clear Cover

Indications for Use *(Describe)*
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.

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

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K211270

1. Submitter's Identifications:

Establishment:	CIVCO Medical Instruments Co., Inc.
Address:	102 First Street South Kalona, IA 52247
Registration Number:	1937223
Operations Manufacturer Owner/Operator:	CIVCO Medical Instruments Co., Inc.
Owner/Operator Number:	1937223
Contact Person:	Jim Leong
Phone:	319-248-6502
e-mail:	James.Leong@civco.com

2. Date 510(k) Summary Prepared: April 21, 2021

3. Name of the Subject Device and Classification Information:

Trade/Device Name	CIV-Clear cover
Regulation Number	21 CFR 892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	Class II
Product Code	ITX

4. Information for the Predicate Device:

Tradename/Device Name	Envision™ Ultrasound Cover and Pad
Manufacturer	CIVCO Medical Instruments Co., Inc.
510(k) Number	K190802
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	II
Product Code	ITX

5. Information for Reference Device:

Tradename/Device Name	EcoVue® Sterile and Non-Sterile Ultrasound Gels
Manufacturer	HR Pharmaceuticals, Inc.
510(k) Number	K181363
Regulation Number	892.1570
Classification Name	Diagnostic ultrasonic transducer
Regulatory Class	II
Product Code	MUI

6. Device Description:

The CIV-Clear cover is a microbial barrier for use during ultrasound procedures. The cover is offered in sterile and non-sterile configurations in a variety of sizes to function with different equipment. The material has been tested and proven to be a viral barrier for microbes 27 nanometers and larger in size.

7. Intended Use / Indications for Use:

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.

8. Clinical Use Envirionment:

The covers are to be used in the healthcare environment where equipment is being utilized.

9. Comparison to Legally Marketed Device

Item		Subject Device CIVCO CIV-Clear Cover K21XXXX	Predicate Device CIVCO Envision Cover and Pad K190802
Material		N/A	Pad: Polycarbonate, silicone elastomer, polyether polyurethane, coating formulation
		Cover: Ethyl Methyl Acrylate (EMA) and Polyethylene blend	Cover: Polyurethane
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
Acoustic Performance	Acoustic Impedance	1.54 ± 0.13 *x* 10^5 *g/(cm^2 sec)*	Primary coating: 1.69 ± 0.18 *x* 10^5 *g/(cm^2 sec)* Secondary coating: 1.68 ± 0.29 *x* 10^5 *g/(cm^2 sec)*
	Acoustic Velocity	1630 m/s	Primary Coating: 1594 m/s Secondary Coating: 1631 m/s
	Density of Coating	N/A – no coating	Primary: 1.06 g/mL) Secondary: 1.03 g/mL
	pH of coating	N/A – no coating	7.11 (both primary and secondary coatings)
Acoustic Coupling		Uses gel to facilitate coupling	Hydrated coating used to facilitate coupling
Sterilization		Ethylene Oxide	Ethylene Oxide
Shelf-life		3 years	3 years
Accessory		Ultrasound gel packet	Saline wipe to facilitate coupling

10. Comparison of Indications to the Legally Marketed Device:

The proposed CIV-Clear devices have the same intended use, of being a microbial barrier, as the legally marketed device. Any differences in the indications for use statement would not affect the safety or effectiveness of the device because the safety and efficacy related to the indicated procedures is dictated by the use of the underlying ultrasound equipment, and the ultrasound cover is secondary to the ultrasound use. Any questions related to safety and effectiveness of the CIV-Clear cover have been addressed using the same testing performed by the legally marketed device, including biocompatibility, viral penetration, and material strength and elasticity studies.

11. Summary of Non-Clinical Tests Performed:

- Biocompatibility:
  The CIV-Clear devices met ISO 10993-1 biocompatibility requirements for limited contact duration for surface devices of breached or compromised surface and external communicating indirect tissue contact:
  - Cytotoxicity – ISO 10993-5
  - Sensitization – ISO 10993-10
  - Irritation – ISO 10993-10
  - Acute Systemic Toxicity – ISO 10993-11
  - Material Mediated Pyrogen – ISO 10993-11

- Viral Penetration:
  The CIV-Clear cover's ability to withstand viral penetration was performed to evaluate the barrier performance of the material in accordance with ASTM F1671-13. Testing has demonstrated the ability to block microbes of size 27 nanometers and larger.

- Water leak testing:
  Water leak testing was performed to demonstrate material strength and elasticity of the CIV-Clear device after sterilization, shipping/conditioning, and aging.

- Acoustic Impedance:
  The measurement of acoustic impedance was performed to compare the acoustic characteristics of the CIV-Clear cover to the predicate cover with coating.

- Simulated Use Testing
  Simulated use testing was performed to ensure the design of the CIV-Clear cover conforms to the user needs and intended use.

- Packaging and Shelf-life:
  CIV-Clear packing uses the same packaging as the predicate device which has been validated per ISO 11607-2 and ISTA 3A parameters to ensure the packaging

maintains its integrity over the course of the device's shelf-life. Accelerated aging in support of a three-year shelf life of product was completed in accordance with ASTM F1980-16.

- Ethylene Oxide Sterilization Validation and Residual Testing:
  The CIV-Clear devices are processed using sterilization cycle validated per ISO 11135 to ensure that the devise meet the required sterility assurance level, so the devices remain adequately free from viable microorganisms following sterilization.

  The sterile CIV-Clear covers qualified for 2x Ethylene Oxide sterilization and tested to ensure that residual levels do not exceed the limits per ISO 10993-7 for contact.

12. Clinical Test Performed:

Clinical tests were not required to demonstrate substantial equivalence.

13. Conclusions:

The CIV-Clear device has the same intended use and its technological characteristics do not raise any different questions of safety or effectiveness, as compared to the legally marketed device. Therefore, the CIV-Clear covers are substantially equivalent to the legally marketed Envision device.