DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 9, 2017

CIVCO Medical Instruments Co., Inc.
Mr. Kevin Mader
Quality Assurance and Regulatory Affairs Manager
6 Winter Avenue
Deep River, Connecticut 06417

Re: K163313
Trade/Device Name: ASTRA TEE® Transesophageal Probe Reprocessor and ASTRA VR™ Endovaginal/Endorectal Probe Reprocessor
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: May 10, 2017
Received: May 11, 2017

Dear Kevin Mader:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163313

Device Name
ASTRA TEE® Transesophageal Probe Reprocessor

Indications for Use *(Describe)*
The ASTRA TEE® automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 transesophageal ultrasound probes using FDA cleared and Civco Medical Solutions approved high-level liquid disinfectants.

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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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:

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163313

Device Name
ASTRA VR™ Endovaginal/Endorectal Probe Reprocessor

Indications for Use *(Describe)*
The ASTRA VR™ automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 endovaginal and/or endorectal ultrasound probes using FDA cleared and Civco Medical Solutions approved high-level liquid disinfectants.

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.

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K163313

510(k) SUMMARY

Submitter	Civco Medical Instruments Co., Inc. d/b/a Civco Medical Solutions 6 Winter Avenue Deep River, CT 06417
Establishment Registration/Owner Operator No.'s	3010661106/1937223
Contact Person	Kevin Mader Manager of Quality & Regulatory kevin.mader@civco.com (319) 248-7777 (Phone) (860) 526-3081 (fax)
Date Prepared	June 1st 2017
Trade Name(Common Name)	ASTRA TEE® (Transesophageal Probe Reprocessor) ASTRA VR™ (Endovaginal/Endorectal Probe Reprocessor)
Regulation Name	Diagnostic Ultrasonic Transducer, 21 CFR 892.1570
Classification	Class II
Product Code	ITX
Predicate Device(s)	ASTRA TEE™ (Transesophageal Probe Reprocessor) ASTRA VR™ (Endovaginal/Endorectal Probe Reprocessor) K150504

Intended Use

For the ASTRA TEE® -

> *The ASTRA TEE® automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 transesophageal ultrasound probes using FDA cleared and Civco Medical Solutions approved high-level liquid disinfectants.*

For the ASTRA VR™ -

> *The ASTRA VR™ automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 endovaginal/endorectal ultrasound probes using FDA cleared and Civco Medical Solutions approved high-level liquid disinfectants.*

The intended use statements are the same to the predicate devices (K150504) with the following minor differences:

- GUS was removed due to marketing reasons (i.e. the GUS trademark does not encompass probe reprocessors).
- The ™ for ASTRA TEE was replaced with ® (update as per registrations as per USPTO)
- 'PCI Medical' was replaced with 'Civco Medical Solutions' (due to change in ownership of the company and products)

The differences in wording used does not change the intended use of the device and hence does not raise new questions of safety or efficacy.

Device Description

The ASTRA Product Family of automated reprocessors are floor standing electromechanical lab equipment that facilitate high-level liquid disinfection of ultrasound probes that have been enzymatically pre-cleaned.

Model types

The ASTRA family of products contains two models 1) ASTRA TEE® for Transesophageal Probes and 2) ASTRA VR™ for Endovaginal/Endorectal probes.

Physical Characteristics

The two models are floor standing units with the following physical characteristics:

ASTRA TEE®

- Width: 12.0" (30.5 cm)
- Depth: 14.0" (35.6 cm)
- Height: 65.0" (165.0 cm)
- Weight: 73 lbs. (33.1 kg)

ASTRA VR™

- Width: 12.0" (30.5 cm)
- Depth: 14.0" (35.6 cm)
- Height: 53.0" (134.6 cm)
- Weight: 73 lbs. (33.1 kg)

Materials

The ASTRA TEE® and ASTRA VR™ automated reprocessors are comprised of the same materials. Only the shape and length of the disinfection chamber and the probe cable restraining designs differ in order to properly accommodate the differences between TEE and VR ultrasound probes. Materials for various components include:

- Metal cabinetry and door – Galvannealed steel

- Adjustable feet – Steel, polyethylene
- Plastic tubes and fittings – Polyvinyl Chloride (PVC), Polyethylene, Polypropylene, EPDM, Stainless Steel, Polycarbonate, Polyurethane, Polysulfone
- Valves – EPR, Polyvinyl Chloride, Stainless Steel
- Plastic disinfection tubes and chamber – Polycarbonate, ABS, Polypropylene.
- Electromechanical sensors, switches, user interface – polyphernylene Sulfide resin, Acryl resin, Polycarbonate resin, stainless steel, silicone, silver, polyester.
- Plastic cover – Polycarbonate
- Diaphragm Pumps – Polypropylene, EPDM, Santoprene
- Electronics and wire harnesses – RoHS compliant electronics, PVC, Copper
- Metal fasteners – Stainless Steel
- Air Filter – Polyester, Silicone, Carbon
- Water filter – Polysulfone, Polypropylene, Silicone

Component selection was carefully performed to select materials that have appropriate electrical safety rating, fire safety rating, and to be compatible with select FDA cleared HLDs. No material changes were made from the predicate device.

Differences

Both reprocessors are derived from the same base unit (identical software, electronics, plumbing, valves, sensors, warming pad, cabinet, etc.) which is configurable to become either a ASTRA TEE® or ASTRA VR™ based on customer demand. To configure a base unit, TEE and VR specific components (e.g. disinfection chamber, chamber door, cable holder, etc.) are used to accommodate the differences between TEE and VR ultrasound probe geometries.

Device Operational Overview

The ASTRA Product Family of automated reprocessors are designed to control the temperature of the high-level liquid disinfectant (HLD), the disinfection time and the rinse cycles used to disinfect ultrasound probes in accordance with HLD manufactures' instructions. The system automatically loads the appropriate preset parameters based on the barcode of the scanned HLD bottle. After the probes are enzymatically pre-cleaned per hospital protocol, reprocessing in the ASTRA is initiated through the use of a simple user interface. The operator presses Enter to start the cycle and uses the onboard barcode reader to scan and load 1 or 2 probes and to scan their ID. The operator then enters the HLD's MRC status at the next prompt. The user will be notified of the probe's disinfection status upon completion of the disinfection cycle. The ASTRA systems use select FDA cleared high-level liquid disinfectant to safely and effectively disinfect medical devices. By automating the disinfection process through validated software and hardware, the ASTRA Product Family of automated reprocessors help users improve their

disinfection outcomes by controlling and tracking the critical process parameters and recording the key operational data.

The ASTRA TEE® and ASTRA VR™ are automated reprocessors which are identical with the exception of the disinfection chamber configuration necessary to compensate for two different types of ultrasound probes. The ASTRA TEE® is an automated reprocessor which enables high-level disinfection and rinsing for transesophageal (TEE) ultrasound probes. The ASTRA VR™ is an automated reprocessor which enables high-level disinfection and rinsing for endovaginal and/or endorectal ultrasound probes.

Both ASTRA systems utilize predefined programs based upon the high-level liquid disinfectant (HLD) used during the disinfection and potable water rinsing cycles. The system controls the HLD temperature and cycle times which are fixed, no user configuration is available. The device will perform the defined automated disinfection and rinsing cycles based upon the HLD specifications. The microprocessor controlled interface monitors temperature and liquid levels of the HLD in the disinfection chamber and the reservoir. Optical sensors are used for HLD reservoir presence and probe identification. Additional user inputs include unique probe identification (for disinfection records) and the results entry of the Minimum Recommended Concentration (MRC) test using test strips and minimum concentration levels as defined by the HLD manufacturer. A sensor located on the disinfection chamber door is used to initiate the cycle after the user has input the required information. User retrievable data/information regarding reprocessing is accessible through a USB port.

Performance Characteristics

The ASTRA Product Family of automated reprocessors utilizes the same technology and high-level disinfection approach employed by the predicate devices, cleared under K150504. Only the software has been re-activated to recognize the additional HLDs (Cidex OPA and Resert XL) originally targeted as part of K150504 for approval as part of this current Traditional 510k submission. The ASTRA controls time, temperature, and rinse parameters used to facilitate a ≥6 Log reduction by the select FDA approved HLDs. As a result, this submission primarily focuses on the performance specification of the instrument and controls (time, temperature, and rinse) common to both devices as it relates to the select HLDs.

The ASTRA systems control the HLD temperature, soak time, and rinse cycle to facilitate ≥6 Log reduction of *M. terrae* on enzymatically cleaned probes.

Device Name	Manufacturer	510(k)	Performance Attribute
ASTRA TEE™ (Transesophageal Probe Reprocessor) ASTRA VR™ (Endovaginal/Endorectal Probe Reprocessor)	Civco Medical Solutions	K163313	Control the HLD temperature, soak time, and rinse cycle to achieve ≥6 Log reduction of *M. terrae using Metricide OPA Plus, Cidex OPA, and Resert XL*

Performance Specifications

The ASTRA Product Family of automated reprocessors share common hardware and software with minor differences necessary to accommodate the different ultrasound probes (TEE and VR) and different HLDs. The intended use and function of the automated reprocessors are the same and they are substantially equivalent to the predicate in design and function. The ASTRA series of automated reprocessors control the HLD temperature, soak time, and rinse cycle to facilitate ≥6 Log reduction of *M. terrae* on enzymatically cleaned probes, thus achieving equivalent performance to the ASTRA systems cleared under K150504.

Device Name	Manufacturer	510(k)	Performance Attribute
ASTRA TEE®/ASTRA VR™ Ultrasound Probe Reprocessors	Civco Medical Solutions	K150504	Control the HLD temperature, soak time, and rinse cycle to facilitate ≥6 Log reduction of *M. terrae* using Metricide OPA Plus

Clinical/Non-Clinical Performance Testing Summary

- The ASTRA system maintains time and temperature required for disinfection as per HLD manufacturers' specifications.
- The ASTRA system passed Safety and EMC testing
- The ASTRA system passed Simulated use and Residual testing
- The ASTRA system passed In-use testing

Technology Comparison to Predicate Devices

The ASTRA Product Family of automated reprocessors utilizes the same technology employed by the predicate device, ASTRA TEE® and ASTRA VR™ cleared under K150504. The ASTRA systems control the HLD temperature, soak time, and rinse cycle for the safe and effective disinfection of ultrasound probes.

Summary of Predicate Comparisons (affected items/changes are in **BOLD** font)				
Characteristic	**Predicate – ASTRA TEE® PCI medical**	**Predicate – ASTRA VR™ PCI medical**	**ASTRA TEE® Civco Medical**	**ASTRA VR™ Civco Medical**
Regulatory				
510(k) Number	K150504	K150504	K163313	K163313
Product Code	ITX	ITX	*Same as predicate*	*Same as predicate*
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	*Same as predicate*	*Same as predicate*
Regulation Name	Diagnostic ultrasonic transducer	Diagnostic ultrasonic transducer	*Same as predicate*	*Same as predicate*
Intended Use/ Indications for Use (differences in **bold** font)	The **GUS** ASTRA TEE™ automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 transesophageal ultrasound probes using FDA cleared and **PCI** Medical approved high-level liquid disinfectants.	The **GUS** ASTRA VR™ automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 endovaginal and/or endorectal ultrasound probes using FDA cleared and **PCI** Medical approved high-level liquid disinfectants.	The ASTRA TEE® automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 transesophageal ultrasound probes using FDA cleared and **Civco** Medical **Solutions** approved high-level liquid disinfectants.	The ASTRA VR™ automated reprocessor facilitates high-level disinfection and rinsing of 1 or 2 endovaginal and/or endorectal ultrasound probes using FDA cleared and **Civco** Medical **Solutions** approved high-level liquid disinfectants.
Prescription Use	No	No	*Same as predicate*	*Same as predicate*
Types of probes	Transesophageal (TEE) probes	Endorectal, endovaginal (VR) probes	*Same as predicate*	*Same as predicate*
Technology and Materials				
Theory of Operation	• Control time, temperature and fluid levels to maintain optimal conditions for disinfection and rinsing as established by HLD manufacturers	• Control time, temperature and fluid levels to maintain optimal conditions for disinfection and rinsing as established by HLD manufacturers	*Same as predicate*	*Same as predicate*
Disinfection time control	• Timing Chip & Software	• Timing Chip & Software	*Same as predicate*	*Same as predicate*
Disinfection temperature control	• Temperature sensor & Software	• Temperature sensor & Software	*Same as predicate*	*Same as predicate*
HLD warming capability	• Yes (Warmer pad)	• Yes (Warmer pad)	*Same as predicate*	*Same as predicate*
Liquid Level Control (HLD and rinse)	• Sensors (upper/lower) & Software	• Sensors (upper/lower) & Software	*Same as predicate*	*Same as predicate*
Overflow Protection	• Sensor (overflow) & Software	• Sensor (overflow) & Software	*Same as predicate*	*Same as predicate*
Probe Detection	• Sensor	• Sensor	*Same as predicate*	*Same as predicate*

Summary of Predicate Comparisons (affected items/changes are in **BOLD** font)				
Characteristic	**Predicate – ASTRA TEE® PCI medical**	**Predicate – ASTRA VR™ PCI medical**	**ASTRA TEE® Civco Medical**	**ASTRA VR™ Civco Medical**
	(microswitch) & Software	(microswitch) & Software		
HLD Vapor Control	• Door, fan & filter	• Door, fan & filter	*Same as predicate*	*Same as predicate*
User Interface	• Text based interface • 4 button keypad • USB port • Barcode Scanner	• Text based interface • 4 button keypad • USB port • Barcode Scanner	*Same as predicate*	*Same as predicate*
HLD MRC Verification	• Operator must verify MRC	• Operator must verify MRC	*Same as predicate*	*Same as predicate*
Material Components	• Diaphragm Pump • Solenoid valves • Polyethylene tubing • Push Fit fittings • Powder coated sheet metal cabinet with ABS plastic components	• Diaphragm Pump • Solenoid valves • Polyethylene tubing • Push Fit fittings • Powder coated sheet metal cabinet with ABS plastic components	*Same as predicate*	*Same as predicate*
Compatible HLDs (differences in **bold** font)	• Uses FDA cleared HLDs (Metricide OPA) per manufacturer's specifications	• Uses FDA cleared HLDs (Metricide OPA) per manufacturer's specifications	• Uses FDA cleared HLD (Metricide OPA, **Cidex OPA and Resert XL**) per manufacturer's specifications	• Uses FDA cleared HLD (Metricide OPA, **Cidex OPA and Resert XL**) per manufacturer's specifications
Disinfectant Usage (differences in **bold** font)	Approved for re-use per HLD Manufacturer's specifications • OPA up to 14 days • Or when MRC test fails	Approved for re-use per HLD Manufacturer's specifications • OPA up to 14 days • Or when MRC test fails	*Same as predicate* with the addition of "**Resert XL up to 21 days"** Cidex OPA usage specifications are identical to Metricide OPA	*Same as predicate* with the addition of "**Resert XL up to 21 days"** Cidex OPA usage specifications are identical to Metricide OPA
Rinse water	Potable water filtered with FDA cleared 0.2µm bacteria retention filter	Potable water filtered with FDA cleared 0.2µm bacteria retention filter	*Same as predicate*	*Same as predicate*
Rinsing	Per HLD Manufacturer's specifications	Per HLD Manufacturer's specifications	*Same as predicate*	*Same as predicate*

Summary of Predicate Comparisons (affected items/changes are in **BOLD** font)				
Characteristic	**Predicate – ASTRA TEE® PCI medical**	**Predicate – ASTRA VR™ PCI medical**	**ASTRA TEE® Civco Medical**	**ASTRA VR™ Civco Medical**
Do Technical differences raise new questions of safety & efficacy to that of the predicate device?				
Base Technology	Time and temperature management	Time and temperature management	*Same as predicate*	*Same as predicate*
Liquid Level Control	• HLD level control by sensor • Rinse level control by sensor	• HLD level control by sensor • Rinse level control by sensor	*Same as predicate*	*Same as predicate*
User interface	• Barcode scanner accepts input data	• Barcode scanner accepts input data	*Same as predicate*	*Same as predicate*
Device characteristics that ensure comparable safety & efficacy to the predicate device (non-clinical testing)				
Control of Critical parameters	Device repeatedly maintains time and temperature required for disinfection	Device repeatedly maintains time and temperature required for disinfection	*Same as predicate*	*Same as predicate*
Efficacy (Disinfection and Residual testing)	Pass as per simulated use (6_{log} reduction of *M. terrae),* In-use Testing (complete kill) and residual testing (ISO10993-5 cytotoxic effect of <= 2)	Pass as per simulated use (6_{log} reduction of *M. terrae),* In-use Testing (complete kill) and residual testing (ISO10993-5 cytotoxic effect of <= 2)	*Same as predicate*	*Same as predicate*
UL 61010 electrical safety	Pass as per METLabs testing	Pass as per METLabs testing	*Same as predicate*	*Same as predicate*
Electromagnetic (EMC) compatibility	Pass as per METLabs testing	Pass as per METLabs testing	*Same as predicate*	*Same as predicate*

Summary of Functional and Safety Testing

Verification and validation was performed for the ASTRA Product Family of automated reprocessors in accordance with following design control regulations, risk management standards, and established quality assurance processes within Civco Medical Solutions' Quality Management System to demonstrate substantial equivalence to the predicate device and to confirm safety and efficacy:

- 21 CFR Part 820.30 Design Controls
- ISO 14971 Medical devices – Application of risk management to medical devices
- ISO 10993-5 Tests for in vitro cytotoxicity
- EN 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests

- UL 61010-1/CSA C22.2 No. 61010-1 Standard for safety electrical equipment for measurement, control and laboratory use; Part 1: general requirements
- EN 61326-1 Electrical equipment for measurement, control and laboratory use – EMC requirements — Part 1: General requirements
- ANSI/AAMI/IEC 62304 Medical Device Software – Software life cycle processes
- ANSI/AAMI HE75 Human factors engineering – Design of medical devices
- Software Verification & Validation, Simulated Use Testing, and In-Use Testing
- HLD Stress/Re-use testing as per EPA guidelines
- Material Compatibility Testing
- Management of Cybersecurity in Medical Devices - Cybersecurity testing

Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective and performs as well as or better than the predicate device.