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

May 30, 2017

PCI Medical, Inc.
Mr. Kevin Mader
Director of Quality and Regulatory
6 Winter Avenue
Deep River, CT 06417

Re: K150504
Trade/Device Name: GUS ASTRA TEE™ Transesophageal Probe Reprocessor
GUS ASTRA VR™ Endovaginal/Endorectal Probe Reprocessor
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: PSW
Dated: October 16, 2015
Received: October 16, 2015

Dear Mr. Kevin Mader:

This letter corrects our substantially equivalent letter of November 16, 2015.

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 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,

Tina Kiang, Ph.D.
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)*
K150504

Device Name
GUS ASTRA TEE™ Transesophageal Probe Reprocessor

Indications for Use *(Describe)*
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.

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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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)*
K150504

Device Name
GUS ASTRA VR™ Endovaginal/Endorectal Probe Reprocessor

Indications for Use *(Describe)*
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.

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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510(k) SUMMARY

Submitter	PCI Medical, Inc. 6 Winter Avenue Deep River, CT 06417
Contact Person	Kevin Mader Director of Quality & Regulatory k.mader@pcimedical.com (800) 862-3394 ext. 247 (860) 526-3081 (fax)
Date Prepared	November 13th 2015
Trade Name(Common Name)	
Regulation Name	Diagnostic Ultrasonic Transducer, 21 CFR 892.1570
Classification	Class II
Product Code	ITX
Predicate Device(s)	CS MEDICAL TD-100 Transesophageal Probe Disinfector, K051305

Intended Use

cilitates high-level disinfection and rinsing of 1 or 2 transesophageal ultrasound probes using FDA cleared and PCI Medical approved high-level liquid disinfectants.

ates high-level disinfection and rinsing of 1 or 2 endovaginal/endorectal ultrasound probes using FDA cleared and PCI Medical approved high-level liquid disinfectants.

The intended use statements use similar language to the predicate TD-100 device (K051305). The differences in wording used does not raise new questions of safety or efficacy.

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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 GUS ASTRA family of products contai

Physical Characteristics

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

-
-
-
- Weight: 73 lbs. (33.1 kg)

-
-
-
- Weight: 73 lbs. (33.1 kg)

Materials

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:

-
-
- (PVC), Polyethylene, Polypropylene, EPDM, Stainless Steel, Polycarbonate, Polyurethane, Polysulfone
-
- Polycarbonate, ABS, Polypropylene.
- Sulfide resin, Acryl resin, Polycarbonate resin, stainless steel, silicone, silver, polyester.

-
-
- compliant electronics, PVC, Copper
-
-
- 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.

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 er 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

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 s MRC status at the next prompt. The user will on 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 GUS ASTRA TEE and GUS 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 GUS ASTRA TEE is an automated reprocessor which enables high-level disinfection and rinsing for transesophageal (TEE) ultrasound probes. The GUS 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 device, the TD-100 cleared under K051305. It should be noted that TD-100 system is comprised of the instrument and proprietary TD-5 HLD. The TD-100 controls time, temperature, and rinse parameters using the TD-5 proprietary HLD to achieve a ≥6 Log reduction. The ASTRA controls time, temperature, and rinse parameters to facilitate a ≥6 Log reduction by the FDA approved HLD. As a result, this submission primarily focuses on the performance specification of the instrument and controls (time, temperature, and rinse) common to both devices.

The ASTRA system and the TD-100 both 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
TD-100 Transesophageal Probe Disinfector System	CS Medical, Inc.	K051305	Control the HLD temperature, soak time, and rinse cycle to achieve ≥6 Log reduction of *M. terrae using proprietary TD-5 HLD*

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). The intended use and function of the automated reprocessors are the same and they are substantially equivalent to the TD-100 probe disinfector 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 at each site tested, thus achieving equivalent performance to the TD-100 instrument.

Device Name	Manufacturer	510(k)	Performance Attribute
Probe Reprocessors	PCI Medical, Inc.	K150504	Control the HLD temperature, soak time, and rinse cycle to facilitate ≥6 Log reduction of *M. terrae* at each site tested using FDA cleared Metricide OPA.

Clinical/Non-Clinical Performance Testing Summary

- The ASTRA system maintains time and temperature required for disinfection as per HLD

- The ASTRA system passes Safety and EMC testing
- The ASTRA system passes simulated use and residual testing
- The ASTRA system passes In-use testing

Technology Comparison to Predicate Devices

The ASTRA Product Family of automated reprocessors utilizes the same technology employed by the predicate device, the TD-100 cleared under K051305. The ASTRA system and the TD-100 both control the HLD temperature, soak time, and rinse cycle for the safe and effective disinfection of ultrasound probes.

Summary of Predicate Comparisons				
Characteristic	**GUS ASTRA TEE PCI medical**	**GUS ASTRA VR PCI medical**	**TD-100 CS Medical**	
Regulatory				
510(k) Number	K150504	K150504	K051305	*N/A*
Product Code	ITX	ITX	ITX	*ASTRA TEE and ASTRA VR same as predicate.*
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	21 CFR 892.1570	*ASTRA TEE and ASTRA VR same as predicate.*

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Summary of Predicate Comparisons				
Characteristic	**GUS ASTRA TEE PCI medical**	**GUS ASTRA VR PCI medical**	**TD-100 CS Medical**	
Regulation Name	Diagnostic ultrasonic transducer	Diagnostic ultrasonic transducer	Diagnostic ultrasonic transducer	*ASTRA TEE and ASTRA VR same as predicate.*
Intended Use/ Indications for Use	The GUS ASTRA 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.	 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 TD-100 disinfector is designed to provide high-level disinfection of Transesophageal (TEE) ultrasound probes. The system uses the TD-5 disinfectant, which is designed to be used only with the TD-100. The disinfectant bottles cannot be reused in the system. TD-5 is intended for use as a single use high-level disinfectant to be used exclusively in the TD-100 for high level disinfection of TEE ultrasound probes. The TD-5 High Level Disinfectant and TD-100 disinfector system is intended for use by qualified individuals trained in its use.	*ASTRA TEE and ASTRA VR similar to predicate:* • *Both are intended for use with FDA cleared High-level Liquid Disinfectants (HLDs) to disinfect ultrasound probes and are to be used by trained personnel in non-sterile healthcare settings* *ASTRA TEE:* • *The ASTRA TEE can reprocess up to 2 TEE probes; TD-100 does 1 TEE probe at a time* • *The ASTRA TEE uses select FDA cleared HLDs; TD-100 uses proprietary HLD* • *The ASTRA TEE re-uses HLD; TD-100 uses a single-use bottle* *ASTRA VR:* • *The ASTRA VR can reprocess up to 2 endovaginal/endorectal ultrasound probes; TD-100 does 1 TEE probe at a time* • *The ASTRA VR uses select FDA cleared HLDs; TD-100 uses proprietary HLD* • *The ASTRA VR re-uses HLD; TD-100 uses a single-use bottle*
Prescription Use	No	No	No	*ASTRA TEE and ASTRA VR same as predicate.*
Types of probes	Transesophageal (TEE) probes	Endorectal, endovaginal (VR) probes	Transesophageal probes	*(TD-100)* *ASTRA VR* *equivalent to TD-100 as both reprocess non-lumened ultrasound probes of various geometries*

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Summary of Predicate Comparisons				
Characteristic	**GUS ASTRA TEE PCI medical**	**GUS ASTRA VR PCI medical**	**TD-100 CS Medical**	
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	• Control time, temperature and fluid levels to maintain optimal conditions for disinfection and rinsing as established by HLD manufacturer	*ASTRA TEE and ASTRA VR same as predicate.*
Disinfection time control	• Timing Chip & Software	• Timing Chip & Software	• Electronics & Software	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. Time control parameters are contingent to HLD Type and manufacturer specifications.*
Disinfection temperature control	• Temperature sensor & Software	• Temperature sensor & Software	• Electronics & Software	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. Temperature control parameters are contingent to HLD Type and manufacturer specifications.*
HLD warming capability	• Yes (Warmer pad)	• Yes (Warmer pad)	• Yes (Unknown)	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*
Liquid Level Control (HLD and rinse)	• Sensors (upper/lower) & Software	• Sensors (upper/lower) & Software	• Sensor (upper) & Software • Fixed volume single use bottle (HLD)	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. HLD Level control TEE and ASTRA VR use sensors to detect when HLD level is met. Predicate uses a pre-measured HLD single use bottle Rinse Water Level: ASTRA TEE and ASTRA VR same as predicate.*
Overflow Protection	• Sensor (overflow) & Software	• Sensor (overflow) & Software	• Sensor (overflow) & Software	*ASTRA TEE and ASTRA VR same as predicate.*
Probe Detection	• Sensor (microswitch) & Software	• Sensor (microswitch) & Software	• Sensor (microswitch) & Software	*ASTRA TEE and ASTRA VR same as predicate.*
HLD Vapor Control	• Door, fan & filter	• Door, fan & filter	• Door, fan & filter	*ASTRA TEE and ASTRA VR same as predicate.*
User Interface	• Text based interface • 4 button keypad • USB port	• Text based interface • 4 button keypad • USB port	• Text based interface • 15 button keypad • Printer	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. ASTRA TEE and ASTRA VR utilize USB port to download data while predicate uses printable data. ASTRA TEE and ASTRA VR*

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Summary of Predicate Comparisons				
Characteristic	**GUS ASTRA TEE PCI medical**	**GUS ASTRA VR PCI medical**	**TD-100 CS Medical**	
	• Barcode Scanner	• Barcode Scanner		*utilize Barcode Scanner to capture input data while the predicate device allows manual input through keypad.*
HLD MRC Verification	• Operator must verify MRC	• Operator must verify MRC	• Operator must verify HLD expiration date	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*
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	• Diaphragm Pump • Solenoid valves • Polyethylene tubing • Fittings • ABS Plastic cabinet	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*
Compatible HLDs	• Uses FDA cleared HLDs (Metricide OPA) per specifications	• Uses FDA cleared HLDs (Metricide OPA) per specifications	• Uses TD-100 specific FDA cleared HLD (TD-5) per specifications	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. Temperature and time control parameters are contingent to HLD Type and manufacturer specifications but operate under the same principle.*
Disinfectant Usage	Approved for re-use per HLD specifications • • OPA up to 14 days • Or when MRC test fails	Approved for re-use per HLD specifications • • OPA up to 14 days • Or when MRC test fails	Approved for single use per HLD specifications • Usage through expiry date • MRC test not specified	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. Usage contingent to HLD Type and manufacturer specifications. Usage duration controlled by system software for the ASTRA TEE and ASTRA VR and MRC verification by operator. TD-100 usage controlled by single-use bottle expiry date which is verified by the operator.*
Rinse water	Potable water filtered with FDA cleared 0.2µm bacteria retention filter	Potable water filtered with FDA cleared 0.2µm bacteria retention filter	Potable water.	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. Usage contingent to HLD Type and manufacturer specifications.*
Rinsing	Per HLD specifications	Per HLD specifications	Per HLD specifications	*ASTRA TEE and ASTRA VR same as predicate*

PCI MEDICAL

Summary of Predicate Comparisons				
Characteristic	**GUS ASTRA TEE PCI medical**	**GUS ASTRA VR PCI medical**	**TD-100 CS Medical**	
Base Technology	Time and temperature management	Time and temperature management	Time and temperature management	*ASTRA TEE and ASTRA VR same as predicate. No new questions/concerns of safety and efficacy.*
Liquid Level Control	• HLD level control by sensor • Rinse level control by sensor	• HLD level control by sensor • Rinse level control by sensor	• HLD level control by volume • Rinse level control by sensor	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. HLD Level control TEE and ASTRA VR use sensors to detect when HLD level is met. Predicate uses a pre-measured HLD single use bottle Rinse Water Level: ASTRA TEE and ASTRA VR same as predicate. No new questions/concerns of safety and efficacy.*
User Interface	• Barcode scanner accepts input data	• Barcode scanner accepts input data	• User inputs data via keypad	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100. No new questions/concerns of safety and efficacy.*
testing)				
Control of Critical parameters	Device repeatedly maintains time and temperature required for disinfection	Device repeatedly maintains time and temperature required for disinfection	Device repeatedly maintains time and temperature required for disinfection	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*
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)	Pass as per simulated use (6_{log} reduction of *M. terrae)* and residual testing	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*
UL 61010 electrical safety	Pass as per METLabs testing	Pass as per METLabs testing	UL approved	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*
Electromagnetic (EMC) compatibility	Pass as per METLabs testing	Pass as per METLabs testing	UL approved	*ASTRA TEE and ASTRA VR Substantially equivalent to TD-100.*

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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 assuranc
Management System to demonstrate substantial equivalence to the predicate device and to confirm safety and efficacy:

- 21 CFR Part 820.30 Design Controls
-
- ISO 10993-5 Tests for in vitro cytotoxicity
- 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 measur
  General requirements
- ANSI/AAMI/IEC 62304 Medical Device Soft
-
- System, Software, and Hardware Verification & Validation

Conclusion

Transesophageal Probe Disinfector. Based on the nonclinical tests performed the subject device performs as safely and as effectively as the legally marketed predicate devices, CS Medical TD-100 Transesophageal probe disinfector (K051305).