510(k) Summary - K182891

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CS Medical Trade Name	Common Name	Classification Name
TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants	High level disinfection reprocessing instrument for ultrasonic transducers, liquid	Diagnostic Ultrasound Transducer (21 CFR 892.1570, Product Code PSW)

Legally Marketed Predicate Device

CS Medical TD 100® Transesophageal Probe Disinfector with TD-5® and TD-8® High Level Disinfectants (K160921) – Primary Predicate Device

Reference Device

EVOTECH® Integrated Endoscope Disinfection System (K061899) – Reference Device

Description of the CS Medical TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants

The TEEClean® cleaner disinfector provides cleaning and high-level disinfection of transesophageal (TEE) ultrasound probes when used according to the operating instructions and when used with TEEZyme® enzymatic cleaner and TD-5® or TD-8® disinfectant. The TEEClean® cleaner disinfector is for use only with TEEZyme® enzymatic cleaner and TD-5® or TD-8® disinfectant. Thus, the TEEClean® cleaner disinfector, TEEZyme® enzymatic cleaner, and TD-5® or TD-8® disinfectant represent a dedicated system. Each soiled TEE probe is bedside cleaned to the TEE probe manufacturer's instructions before insertion into the TEEClean® cleaner disinfector. A fresh, unopened bottle of TD-5® or TD-8® disinfectant is loaded into the TEEClean® cleaner disinfector. The TEEClean® cleaner disinfector heats the TEEZyme®, soaks the

TEE probe, and thoroughly rinses the enzymatic cleaner off the TEE probe before the cleaning cycle is complete. The TEEClean® cleaner disinfector then heats TD-5® or TD-®8 disinfectant to 38°-40°C, soaks the TEE probe at least five (5) minutes, and then thoroughly rinses the disinfectant off the TEE probe before the disinfection cycle is complete. The TEEClean® cleaner disinfector prints a verification report indicating a successful cleaning and disinfection cycles as well as the time and the average temperature during the disinfection. The TEE probe is then removed from the TEEClean® cleaner disinfector and dried according to the TEE probe manufacturer's instructions. The TEEClean® cleaner disinfector is ready for a new cycle immediately after the preceding cycle is completed. Because a fresh bottle of TD-5® or TD-8® disinfectant is used with each cycle, no monitoring of the disinfectant's potency is required, nor is there any requirement for daily testing of the disinfectant solution.

Indications for Use Statement

The TEEClean® automated cleaner disinfector is intended to replace manual cleaning of Transesophageal (TEE) ultrasound probes and automate high-level disinfection of TEE probes. The system uses TEEZyme® enzymatic cleaner to clean TEE probes as well as TD-5® or TD-8® disinfectant to high level disinfect TEE probes. TEE probes must undergo bedside cleaning prior to insertion into the TEEClean®.

The TD-5® or TD-8® disinfectant bottles cannot be reused in the system.

TD-5® disinfectant is intended for use as a single use high-level disinfectant used exclusively in the TEEClean® automated cleaner disinfector for high-level disinfection of TEE ultrasound probes. TD-5® disinfectant should be used with the following contact conditions in the TEEClean® automated cleaner disinfector:

High-level Disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-5®	5 minutes	38°-40°C	1.7% glutaraldehyde

TD-8® disinfectant is intended for use as a single use high-level disinfectant used exclusively in the TEEClean® automated cleaner disinfector for high-level disinfection of TEE ultrasound probes. TD-8® disinfectant should be used with the following contact conditions in TEEClean® automated cleaner disinfector:

High-level Disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-8®	5 minutes	38°-40°C	0.3% ortho-phthalaldehyde

TEEZyme® enzymatic cleaner, TD-5® and TD-8® high level disinfectant, and TEEClean® automated cleaner disinfector system are intended for use by qualified individuals trained in its use.

Technological Characteristics:

Comparison of Proposed Device to Reference Device and Primary Predicate Device

Element	**Proposed Device** TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants	**Reference Device** EVOTECH® Integrated Endoscope Disinfection System (K061899)	**Primary Predicate Device** TD 100® Transesophageal Probe Disinfector and TD-5® and TD-8® High- level Disinfectant (K160921)	**Comparison**
Classification Name (CFR; Product code)	Diagnostic ultrasonic transducer (21 C.F.R. § 892.1570, Product Code PSW)	Liquid chemical sterilants/high level disinfectant (21 CFR §876.1500, Product Code FEB)	Diagnostic ultrasonic transducer (21 C.F.R. § 892.1570, Product Code PSW)	Proposed and primary predicate same classification
Indications for use	The TEEClean® automated cleaner disinfector is intended to replace manual cleaning of Transesophageal (TEE) ultrasound probes and automate high-level disinfection of TEE probes. The system uses TEEZyme® enzymatic cleaner to clean TEE probes as well as TD-5® or TD-8® disinfectant to high level disinfect TEE probes. TEE probes must undergo bedside cleaning prior to insertion into the TEEClean®. The TD-5® or TD-8® disinfectant bottles cannot be reused in the system. TD-5® disinfectant is	The EVOTECH® System, a washer/disinfector, is indicated for use with the high level disinfectant CIDEX® OPA Concentrate Solution and an enzymatic detergent (CIDEZYME® GI) to achieve cleaning and high level disinfection of heat sensitive (> 60°C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH® System when selecting those cycles that contain a wash stage. (Manual cleaning of medical devices [endoscopes] is required when selecting the Disinfect Only or Disinfect/Alcohol	The TD 100® disinfector is designed to provide high-level disinfection of Transesophageal (TEE) probes. The system can use TD-5® or TD-8® disinfectants, which are designed to be used only with the TD 100® disinfector. The disinfectant bottles cannot be reused in the system. TD-5® and TD8® disinfectants are intended for use as single use high-level disinfectant to be used exclusively in the TD 100® disinfector for high-level disinfection of TEE ultrasound probes. TD-5® and TD-8® high level disinfectants and TD 100® disinfector system are intended for use by qualified	Proposed device and primary predicate similar indications for use, reference device provides cleaning function

	intended for use as a single use high-level disinfectant used exclusively in the TEEClean® automated cleaner disinfector for high-level disinfection of TEE ultrasound probes. TD-5® disinfectant should be used with the following contact conditions in the TEEClean® automated cleaner disinfector: High-level disinfectant TD-5® Time - 5 minutes Temperature - 38° - 40°C Minimum Recommended Concentration 1.7% glutaraldehyde TD-8® disinfectant is intended for use as a single use high-level disinfectant used exclusively in the TEEClean® automated cleaner disinfector for high-level disinfection of TEE ultrasound probes. TD-8® disinfectant should be used with the following contact conditions in TEEClean® automated cleaner disinfector: High-level disinfectant TD-8® Time - 5 minutes Temperature - 38° - 40°C Minimum Recommended Concentration 0.3% ortho-phthalaldehyde TEEZyme® enzymatic	Flush cycles.)	individuals trained in its use. TD-5® disinfectant should be used with the following contact conditions in TD 100® disinfector: High-level disinfectant TD-5® Time - 5 minutes Temperature - 38° - 40°C Minimum Recommended Concentration 1.7% glutaraldehyde TD-8® disinfectant should be used with the following contact conditions in TD 100® disinfector: High-level disinfectant TD-8® Time - 5 minutes Temperature - 38° - 40°C Minimum Recommended Concentration 0.3% ortho-phthalaldehyde	

	cleaner, TD-5® and TD-8® high level disinfectant, and TEEClean® automated cleaner disinfector system are intended for use by qualified individuals trained in its use.			
Instrumentation For Automation	TEEClean® with TEEZyme® enzymatic cleaner and TD-5® or TD-8® disinfectors is automated for single use with only TD-5® or TD-8® disinfectants. The user initiates the automated cleaning and disinfection cycles via touchpad and receives cleaning and disinfection verification ticket and data is stored electronically.	The EVOTECH® System, utilizes CIDEZYME® GI Enzymatic Detergent and the high level disinfectant CIDEX® OPA Concentrate Solution (ortho-phthalaldehyde). The user initiates the automated process. Data for each step of the process are printed immediately or stored electronically.	TD 100® with TD-5® or TD-8® disinfectors is automated for single use with only TD-5® or TD-8® disinfectants. The user initiates the automated cycle via touchpad and receives disinfection verification ticket.	Proposed device and primary predicate device same, reference device provides cleaning function

Comparison of Proposed Device to Primary Predicate Device

	Proposed Device TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants	**Primary Predicate Device** TD 100® Transesophageal Probe Disinfector and TD-5® and TD-8® High- level Disinfectant (K160921)	**Comparison**
Features			
The system shall utilize a disinfectant that has at least a one year shelf life from the date of manufacture.	Yes	Yes	Same
Single-use disinfectants only	Yes	Yes	Same
User hazard to disinfectant contact reduced by bottle loading system	Yes	Yes	Same
The system shall provide a disinfection cycle that has a	Yes	Yes	Same

disinfectant contact time, at least 300 seconds and temperature 38-40°C			
Disinfectant residues shall be rinsed until the disinfectant residue is below a toxicologically significant level.	Yes	Yes	Same
Reduced height of machine for easy load of TEE probe	Yes	Yes	Same
Machine number, lot number of disinfectant, probe number, operator number on output ticket	Yes	Yes	Same
Minimal footprint, secured to wall for stability	Yes	Yes	Same
Bar code data entry or touchscreen input	Yes	No	See reference device
Separate drain for disinfectant	Yes	No	See reference device
USB port for downloading session reports	Yes	No	See reference device
Internal water filter with service reminder	Yes	No	See reference device
The system shall create a record of every clean and disinfect attempt (e.g., successful, failed, and user aborted cleaning and disinfection cycles, error conditions, etc.) in memory and apply a unique, sequential accession number to each record.	Yes	No	See reference device
The system shall create a record in memory for every error event that occurs and apply a unique, sequential number to each record.	Yes	No	See reference device
The system shall notify users when preventative	Yes	No	See reference device

maintenance is required.			
Design			
Intended Use	Automated cleaning and high-level disinfection of TEE probes	Automated high-level disinfection of TEE probes	Same
Manual Pre-cleaning	Yes	Yes	Same
Operating principles	Enzymatic cleaning and aldehyde high-level disinfection	Aldehyde high-level disinfection	See reference device
Process monitors	Digital display screen, printout	Digital display screen, printout	Same
Software/firmware control	Yes	Yes	Same
Performance claims	Cleaning and High-level disinfection	High-level disinfection	See reference device
Provides high-level disinfection for heat-sensitive TEE probes	Yes	Yes	Same
Uses enzymatic cleaner	Yes	No	See reference device
Uses glutaraldehyde- based disinfectant	Yes	Yes	Same
Uses OPA-based disinfectants	Yes	Yes	Same
Automated disinfection cycle	Yes	Yes	Same
Filter rinse water	Yes	No	See reference device
Disinfection process with success/failure print out.	Yes	Yes	Same
User hazard to vapor exposure controlled by vapor management system utilizing air circulation and activated carbon filtration	Yes	Yes	Same
The system shall be designed to utilize a modular electronics controller box.	Yes	Yes	Same

The system shall be controlled by a microcontroller processor.	Yes	Yes	Same
The system shall provide a built-in printer.	Yes	Yes	Same
Specifications			
Dedicated enzymatic cleaner for use with the device	TEEZyme® Cleaner	No	See reference device
Dedicated Disinfectants for use with the device	Glutaraldehyde (TD-5); Ortho-phthalaldehyde (TD-8)	Glutaraldehyde (TD-5); Ortho-phthalaldehyde (TD-8)	Same
Disinfectant Minimum Recommended Concentration	1.7% glutaraldehyde (TD-5) 0.3% ortho-phthalaldehyde (TD-8)	1.7% glutaraldehyde (TD-5) 0.3% ortho-phthalaldehyde (TD-8)	Same
110 VAC	Yes	Yes	Same
Potable Water Inlet	Yes	Yes	Same
Filter rinse water	Yes	Yes	Same
Direct Drainage to Waste	Yes	Yes	Same

The technological differences between the cleaning phase of the, Proposed Device, TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants and the, Reference Device, EVOTECH® Integrated Endoscope Disinfection System (K061899) are small and are addressed by the use of similar testing methodology for evaluating the performance of the cleaning phase. Both devices used a proprietary, enzymatic detergent to soak the respective probes and achieve cleaning. Both devices used a spectroscopic method to assay protein residues in the test soil before and after cleaning. Both devices used a spectroscopic method to assay carbohydrate/carbon residues in the test soil before and after cleaning.

Comparison of Proposed Device to Reference Device

	Proposed Device TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants	**Reference Device** EVOTECH® Integrated Endoscope Disinfection System (K061899)	**Comparison**
Bar code data entry or	Yes	Yes	Same

touchscreen input			
Separate drain for disinfectant	Yes	Yes	Same
USB port for downloading session reports	Yes	Yes	Same
Internal water filter with service reminder	Yes	Yes	Same
The system shall create a record of every clean and disinfect attempt (e.g., successful, failed, and user aborted cleaning and disinfection cycles, error conditions, etc.) in memory and apply a unique, sequential accession number to each record.	Yes	Yes	Same
The system shall create a record in memory for every error event that occurs and apply a unique, sequential number to each record.	Yes	Yes	Same
The system shall notify users when preventative maintenance is required.	Yes	Yes	Same
Operating principles	Enzymatic cleaning and aldehyde high-level disinfection	Enzymatic cleaning and aldehyde high-level disinfection	Same
Performance claims	Cleaning and High-level disinfection	Cleaning and High-level disinfection	Same
Uses enzymatic cleaner	Yes	Yes	Same
Dedicated enzymatic cleaner for use with the device	TEEZyme® Cleaner	CIDEZYME® GI	Same

Non-Clinical Testing:

Software Validation

All qualification activities defined in the TEEClean® Master Verification and Validation Plan were successfully completed and provided documented evidence that the TEEClean® consistently performs as intended. All data collected during test execution met the established acceptance criteria, was recorded on the data forms, and satisfactorily completed. The TEEClean® Verification and Validation Summary Report

and the associated qualification documents for the TEEClean® detail the successful completion of all requirements of the TEEClean® Master Verification and Validation Plan.

Electrical Safety Testing

The TEEClean® cleaner disinfector has been investigated and passed all testing in accordance with UL 61010-1, 3rd Edition; Standard for Safety, Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements; Rev. April 29, 2016 and UL 61010-2-040, 2nd Edition; Standard for Safety, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used To Treat Medical Materials; Rev. January 15, 2016

Biocompatibility

Rinsing studies were performed on the rinsing the TEE probe shaft receives from the TEEClean cleaner disinfector after cleaning. Measured concentrations of the enzymes (TEEZyme® Cleaner) were taken from the rinse water and were judged acceptable.

Rinsing studies were performed on the rinsing the TEE probe shaft receives from the TEEClean cleaner disinfector after high-level disinfection. Measured concentrations of the disinfectant aldehydes (glutaraldehyde for TD-5® disinfectant, ortho-phthalaldehyde for TD-8® disinfectant) were taken from the rinse water and were judged acceptable.

Cytotoxicity testing was performed on TEE probes reprocessed in the TEEClean® cleaner disinfector with TD-5® and TD-8®. All probes passed and were considered non-cytotoxic.

Performance Testing

Disinfectant (TD-5® and TD-8®) vapor exposure studies were performed in a room with zero air exchanges and showed the main vapor management filter has capacity for 12 months of use.

Automated Simulated use studies with TEEZyme® Cleaner were conducted in the TEEClean® cleaner disinfector. In all cases there was a measurable reduction of soils to levels to allow for subsequent, successful high-level disinfection.

Automated Simulated use studies with TD-5® and TD-8® were conducted in the TEEClean® cleaner disinfector. In all cases there was a measurably complete kill of microorganisms after TEE probe processing.

After routine clinical use, soiled TEE probes were subjected to cleaning and disinfection in the TEEClean® cleaner disinfector with TEEZyme® Cleaner and TD-5® or TD-8® disinfectant with standard operating parameters. In all cases there was a measurably complete kill of microorganisms after TEE probe processing.

Conclusion:

Based on the intended use, technological characteristics and non-clinical performance data, the TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants is as safe, as effective, and performs as well or better than the legally marketed predicate device TD 100® Disinfector with TD-5® and TD-8® High Level Disinfectants (K160921).