April 1, 2020

CS Medical L.L.C.
Kendall Ashe
Vice President and General Manager
2179 East Lyon Station Road
Creedmoor, North Carolina 27522

Re: K192228
Trade/Device Name: TD 200® Disinfector with
TD-12® High Level Disinfectant
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: PSW, MED
Dated: February 27, 2020
Received: February 27, 2020

Dear Kendall Ashe:

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); 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 Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192228

Device Name

TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant

Indications for Use *(Describe)*

The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant is designed to provide high-level disinfection of Transesophageal (TEE) ultrasound probes. The system can use TD-12® disinfectant, which is designed to be used only with the TD 200® disinfector. The disinfectant bottles cannot be reused in the system.

TD-12® disinfectant is intended for use as single use high-level disinfectant to be used exclusively in the TD 200® disinfector for high-level disinfection of TEE ultrasound probes.

TD-12® high level disinfectant and TD 200® disinfector is intended for use by qualified individuals trained in its use.

TD-12® disinfectant should be used with the following contact conditions in TD 200® disinfector:

High-level disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-12®	3 minutes	38°C	1.75% peracetic acid

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

K192228

510(k) Owner
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Contact Name
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Submission Prepared
26-Feb-2020

CS Medical Trade Name	Common Name	Classification Name
TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant	TD 200®	Diagnostic ultrasonic transducer (21 CFR 892.1570, Primary Product Code, PSW Secondary Product Code, MED

Legally Marketed Predicate Devices
1. CS Medical TD 100® Transesophageal Probe Disinfector with TD-5® and TD-8® High Level Disinfectants (K160921) – Primary Predicate
2. Medivators Rapicide PA High Level Disinfectant (K082988)

Reference Device
1. TD-8 High-Level Disinfectant (K160921)

Description of the CS Medical TD 200® Automated Tee Probe Disinfector with TD-12® High Level Disinfectant

The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant provides high-level disinfection of transesophageal (TEE) ultrasound probes when used according to the operating instructions and when used with TD-12® disinfectant. The TD 200® disinfector is for use only with TD-12® disinfectant. The TD-12® is for use only in the TD 200® disinfector. Thus, the TD 200® disinfector and TD-12® disinfectant represent a dedicated system. Each soiled TEE probe is bedside cleaned and manually cleaned according to the TEE probe manufacturer's instructions before insertion into the TD 200® disinfector. A fresh, unopened bottle of TD-12® disinfectant is loaded into the TD 200® disinfector. The TD 200® disinfector heats the TD-12® disinfectant to at least 38°C, soaks the TEE probe at least three (3) minutes, and then thoroughly rinses the disinfectant off the TEE probe before the cycle is complete. The TD 200® disinfector prints a verification report indicating a successful disinfection cycle, the time and the average temperature during the disinfection. The TEE probe is then removed from the TD 200®

disinfector and dried according to the TEE probe manufacturer's instructions. The TD 200® disinfector is ready for a new cycle immediately after the preceding cycle is completed. A chemical indicator is used to ensure that the solution is above the MRC.

Indications for Use Statement

The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant is designed to provide high-level disinfection of Transesophageal (TEE) ultrasound probes. The system can use TD-12® disinfectant, which is designed to be used only with the TD 200® disinfector. The disinfectant bottles cannot be reused in the system.

TD-12® disinfectant is intended for use as single use high-level disinfectant to be used exclusively in the TD 200® disinfector for high-level disinfection of TEE ultrasound probes.

TD-12® high level disinfectant and TD 200® disinfector is intended for use by qualified individuals trained in its use.

TD-12® disinfectant should be used with the following contact conditions in TD 200® disinfector:

High-level disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-12®	3 minutes	38°C	1.75% peracetic acid

Technological Characteristics:

Table C1.a: Comparative Table for TD 200®

Element	Proposed Device TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant (K192228)	Predicate Device TD 100® Transesophageal Probe Disinfector and TD-5 and TD-8 High- level Disinfectant (K160921)	Predicate Device Rapicide PA (K082988)
Classification Name (CFR; Product code)	Diagnostic ultrasonic transducer (21 C.F.R. § 892.1570, product code PSW)	Diagnostic ultrasonic transducer (21 C.F.R. § 892.1570, product code PSW)	Liquid chemical sterilants/high level disinfectant (21 CFR §880.6885, Product Code MED)
Indications for use	The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant is designed to provide high-level disinfection of Transesophageal (TEE) ultrasound probes. The system can use TD-12® disinfectant, which is	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	Rapicide PA High Level Disinfectant is a peracetic acid based, two part disinfectant. Part A contains the active ingredients and Part B contains anticorrosive agents and surfactants. Part A and Part B are mixed in

	designed to be used only with the TD 200® disinfector. The disinfectant bottles cannot be reused in the system. TD-12® disinfectant is intended for use as single use high-level disinfectant to be used exclusively in the TD 200® disinfector for high-level disinfection of TEE ultrasound probes. TD-12® high level disinfectant and TD 200® disinfector is intended for use by qualified individuals trained in its use. TD-12® disinfectant should be used with the following contact conditions in TD 200® disinfector: High-level disinfectant TD-12® Time - 3 Minutes Temperature - 38°C Minimum Recommended Concentration (MRC) 1.75% Peracetic Acid	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 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° to 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° to 40°C Minimum Recommended Concentration	the machine and diluted with water. The Minimum Recommended Concentration (MRC) of Rapicide PA is 850 ppm of peracetic acid. A test strip is used to ensure that the use solution is above the MRC. Rapicide PA High Level Disinfectant is intended for use with the Advantage Plus Endoscope Reprocessing System to provide high level disinfection of endoscopes when used according to the directions for use. Rapicide PA should be used under the following contact conditions: Time – 5 minutes Temperature – 30˚ Minimum Recommended Concentration (MRC) 850ppm

		0.3% ortho-phthalaldehyde	
Instrumentation For Automation	TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant is automated for single use with only TD-12® disinfectant. The user initiates the automated cycle via touchpad and receives disinfection verification ticket. Software has been modified as compared to the predicate TD 100 (K160921) to facilitate the only choice of TD-12® disinfectant. Other aspects of the instrumentation are identical to current TD 100 with TD-5 and TD-8 devices.	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.	Rapicide PA is indicated for manual use and use with undesignated (legally marketed) automatic reprocessors that provide designated contact conditions.

Comparison of Proposed Device to Primary Predicate Device

	Proposed Device TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant (K192228)	**Predicate Device** TD 100® Transesophageal Probe Disinfector and TD-5 and TD-8 High- level Disinfectant (K160921)	**Predicate Device** Rapicide PA (K082988)	**Comparison**
Features				
The system shall utilize a disinfectant that has at least a one year shelf life from the date of manufacture.	Yes	Yes	Yes	Same
Single-use disinfectants only	Yes	Yes	Yes	Same
User hazard to disinfectant contact reduced by bottle loading system	Yes	Yes	N/A	Same
The system shall provide a disinfection cycle that has a disinfectant contact time, at least 180 seconds and disinfects at 38°C	Yes	No	N/A	TD-12 has a shorter disinfection time vs TD 100

Disinfectant residues shall be rinsed until the disinfectant residue is below a toxicologically significant level.	Yes	Yes	N/A	Same
Machine number, lot number of disinfectant, probe number, operator number on output ticket	Yes	Yes	N/A	Same
Design				
Intended Use	Automated high-level disinfection of TEE probes	Automated high-level disinfection of TEE probes	High-level disinfection of endoscopes	Same
Manual Pre-cleaning	Yes	Yes	Yes	Same
Operating principles	Peracetic Acid high-level disinfection	Aldehyde high-level disinfection	Peracetic Acid high-level disinfection	Same (TD-12 and Rapicide PA)
Process monitors	Digital display screen, printout	Digital display screen, printout	N/A	Same
Software/firmware control	Yes	Yes	N/A	Same
Performance claims	High-level disinfection	High-level disinfection	High-level disinfection	Same
Provides high-level disinfection for heat-sensitive TEE probes	Yes	Yes	Yes	Same
Uses PAA-based disinfectants	Yes	No	Yes	Same (TD-12 and Rapicide PA)
Automated disinfection cycle	Yes	Yes	N/A	Same
Disinfection process with success/failure print out.	Yes	Yes	N/A	Same
User hazard to vapor exposure controlled by vapor management system utilizing air circulation and activated carbon filtration	Yes	Yes	N/A	Same
The system shall be designed to utilize a modular electronics controller box.	Yes	Yes	N/A	Same
The system shall be controlled by a microcontroller processor.	Yes	Yes	N/A	Same

The system shall provide a built-in printer.	Yes	Yes	N/A	Same
Specifications				
Dedicated Disinfectants for use with the device	Peracetic acid (TD-12)	Glutaraldehyde (TD-5); Ortho-phthalaldehyde (TD-8)	Rapicide PA peracetic acid	Same (TD-12 and Rapicide PA)
Disinfectant Minimum Recommended Concentration	1.75% Peracetic Acid (TD-12)	1.7% glutaraldehyde (TD-5) 0.3% ortho-phthalaldehyde (TD-8)	850 ppm peracetic acid	Similar (TD-12 and Rapicide PA)
110 VAC	Yes	Yes	N/A	Same
Potable Water Inlet	Yes	Yes	N/A	Same

The technological differences between the high-level disinfection phase of the Proposed Device (TD 200) K192228 and Predicate Device (TD 100) K160921 are small except for the type of high-level disinfectants. The differences between TD-12 and Rapicide PA are small except for the Minimum Recommended Concentration (MRC), which are similar. Both devices, TD 200 and TD 100, achieve the same high-level disinfection of TEE probes using the same technological methods. Both TD-12 and Rapicide PA are peracetic acid high-level disinfectants which achieve high-level disinfection useful for the disinfection of TEE and Endoscopy probes. Both Proposed (TD-12) and Predicate (Rapicide PA) devices have similar physical properties (Table C1.b) and disinfection properties (Table C1.c).

Table C1.b: Comparative Table (Physical Properties) for TD-12®, TD-8®, Rapicide PA

Physical Properties	**Proposed Device** **TD-12®**	**Reference Device** **TD-8**	**Predicate Device** **Rapicide PA**	**Comparison**
510(k) Number	K192228	K160921	K082988	
Active Ingredients	3.0% peracetic acid	0.59% Ortho-phthaladehyde	Part A - 22% hydrogen peroxide and 5% peroxyacetic acid Part B – 4%	Similar (TD-12 and Rapicide PA)
Inert Ingredients	97.0%	99.41%	Part A - 73% Part B – 95.7%	TD-12, TD-8, and Rapicide PA have different inert ingredients
Water-Based Liquid	No	Yes	Yes	Same after hydration of TD-12
pH Value	8.5 – 9.0	7.45 – 7.55	0.4±.3 Part A 11.4 - 12.4 Part B Combined Part A and B is 4.2	TD-12, TD-8, and Rapicide PA have different pH values

Buffer System	Sodium Carbonate and Sulfamic Acid	Phosphates	Trisodium Phosphate	TD-12, TD-8, and Rapicide PA have different buffer system
Minimum Recommended Concentration (MRC)	1.75%	0.3%	850 ppm	TD-12 and Rapicide PA have different MRC
Dilution Required	Yes	No	Yes	Same (TD-12 and Rapicide PA)
Activation Required	Yes	No	Yes	Same (TD-12 and Rapicide PA)
High-Level Disinfection Claim	Yes	Yes	Yes	Same
Sterilization Claim	No	No	No	Same
Maximum Re-Use Period	Single Use	Single Use	28 Days	Same (TD-12 and TD-8). Rapicide PA not single use.
PAA Test Strip Available	Yes	No	Yes	Same (TD-12 and Rapicide PA)
Use in Automated Disinfector	Required	Required	Optional	Same (TD-12 and TD-8). Optional Rapicide PA
Manual Use	No	No	Optional	Same (TD-12 and TD-8). Optional Rapicide PA
Disinfectant Temperature Minimum	38°C	38°C	30°C	Same (TD-12 and TD-8). Rapicide PA has lower Min Temp
Disinfection Time	3 Minutes	5 Minutes	5 Minutes	Similar

Table C1.c: Comparative Table (Test Organism) for TD-12®, TD-8, Rapicide PA

Test Organism	**Proposed Device** **TD-12®**	**Reference Device** **TD-8**	**Predicate Device** **Rapicide PA**	**Comparison**
Sporicidal Bacillus subtilis	5.0 hrs at 37°C	32.0 hrs at 37°C	Total Kill	Same
Sporicidal Clostridium sporogenes	5.0 hrs at 37°C	32.0 hrs at 37°C	Total Kill	Same

Tuberculocidal Mycobacterium terrae	3.0 min at 37°C	5.0 min at 37°C	Total Kill	Same
Bactericidal Staphylococcus aureus	3.0 min at 37°C	5.0 min at 37°C	Total Kill	Same
Bactericidal Salmonella enterica	3.0 min at 37°C	5.0 min at 37°C	Total Kill	Same
Bactericidal Pseudomonas aeruginosa	3.0 min at 37°C	5.0 min at 37°C	Total Kill	Same
Fungicidal Trichophyton mentagrophytes	3.0 min at 37°C	5.0 min at 37°C	Total Kill	Same
Virucidal Poliovirus Type 1	3.0 min at 37°C	5.0 min at 37°C	Complete Inactivation for Polio Virus Type 2	Same (TD-12 and TD-8). Type 2 for Rapicide PA
Virucidal Herpes Simplex Virus Type 1	3.0 min at 37°C	5.0 min at 25°C	Complete Inactivation	Same
Virucidal Human Influenza Virus A	3.0 min at 37°C	5.0 min at 25°C	Not performed	Same (TD-12 and TD-8)
Virucidal Adenovirus Type 1	3.0 min at37°C	5.0min at 25°C	Not performed	Same (TD-12 and TD-8)
Simulated Use Mycobacterium terrae	3.0 min at 37°C	5.0 min at 37°C	>6 log Reduction	Same
Clinical In-Use Wild-type from patients	3.0 min at 37°C	5.0 min at 37°C	Total Kill	Same

Clinical In-Use Testing

After routine clinical use, soiled TEE probes were subjected to disinfection in the TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant using standard operating parameters. In all cases, there was a complete kill of microorganisms after TEE probe processing.

Non-Clinical Testing

Software Validation

All qualification activities defined in the TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant Verification and Validation Plan were successfully completed and provided documented evidence that the TD 200® 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 TD 200® Verification and Validation Summary Report and the associated qualification documents for the TD 200® detail the successful completion of all requirements of the TD 200® Master Verification and Validation Plan.

Electrical Safety Testing

The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant 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.

Clinical In-Use Testing

After routine clinical use, soiled TEE probes were subjected to disinfection in the TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant using standard operating parameters. In all cases, there was a complete kill of microorganisms after TEE probe processing.

Biocompatibility

Under conditions of the study, TD-12® is not a sensitizer, nor an irritant and is non-cytotoxic. Transesophageal probes processed in the TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant were evaluated for disinfectant residue. The analysis indicates that the level of residue on the TEE probes are not likely to have toxic effects on humans.

Material Compatibility

The materials used to construct the TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant were exposed to TD-12® disinfectant for a pre-determined period of time. There were no observable effects from exposure to TD-12® disinfectant onmaterials.

Compatibility Testing with TEE Probes

The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant should be used only with TEE probes which have been tested and approved by TEE probe manufacturers. Material Compatibility has been performed with GE, Philips and Siemens TEE probes. These probes did not have cosmetic nor functional deterioration. TD-12® probe compatibility testing was completed using a use-suspension of 3% w/v (approximately 3000ppm) PAA TD-12® at 38ºC.

Performance Testing

Disinfectant (TD-12®) 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 TD-12® were conducted in the TD 200® 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 disinfection in the TD 200® disinfector with TD-12® disinfectant with standard operating parameters. In all cases there was a measurably complete kill of microorganisms after TEE probe processing.

Stability

TD-12® high level disinfectant has been tested and shown to be stable for a shelf life of at least twelve (12) months.

Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrates that the TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant is as safe, as effective, and performs as well as or better than the legally marketed predicate device Medivators Rapicide PA High Level Disinfectant (K082988).