



November 21, 2023

CS Medical LLC
Kendall Ashe
Vice President, General Manager
2179 East Lyon Station Rd
Creedmoor, North Carolina 27522

Re: K233049

Trade/Device Name: TD 200® Automated TEE Probe Disinfectant with TD-12® High-Level
Disinfectant with QwikCheck™ Chemical Indicator

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic Ultrasonic Transducer

Regulatory Class: Class II

Product Code: PSW, MED, JOJ

Dated: September 25, 2023

Received: September 25, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,


Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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Enclosure

Indications for Use

510(k) Number (if known)
K233049

Device Name

TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant with QwikCheck™ Chemical Indicators

Indications for Use (Describe)

The TD 200® Automated TEE Probe Disinfector with TD-12® High Level Disinfectant with QwikCheck™ Chemical Indicators 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	1750 ppm peracetic acid

QwikCheck™ Chemical Indicators are used prior to the disinfection cycle to ensure that the disinfectant used is above the minimum recommended concentration (MRC) of 1750ppm 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

K233049

510(k) Owner

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Contact Name

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Submission Prepared

25-Sept-2023

CS Medical Trade Name

TD 200[®] Automated TEE Probe
Disinfectant with TD-12[®] High Level
Disinfectant with QwikCheck[™]
Chemical Indicators

Common Name

TD 200 disinfectant
TD-12 disinfectant
and QwikCheck[™]
chemical indicator

Classification Name

Diagnostic ultrasonic
transducer (21 CFR
892.1570, Primary
Product Code, PSW
Secondary Product Code,
MED, JOJ

Legally Marketed Predicate Devices

1. TD 200/TD-12 disinfectant/disinfectant system (K192228) – Primary Predicate
2. IBT Scientific Peracid Test (K964264)

Description of the CS Medical TD 200[®] Disinfectant with TD-12[®] High Level Disinfectant and QwikCheck[™] Indicator

The TD 200 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 disinfectant is for use only with TD-12 disinfectant. The TD-12 is for use only in the TD 200 disinfectant. Thus, the TD 200 disinfectant 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 disinfectant. A fresh, unopened bottle of TD-12 disinfectant is loaded into the TD 200 disinfectant. The TD 200 disinfectant 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 disinfectant 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 disinfectant and dried according to the TEE probe manufacturer's instructions. The TD 200 disinfectant 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.

TD 200, TD-12, and QwikCheck Indications for Use Statement:

The TD 200® 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® disinfectant. 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® disinfectant for high-level disinfection of TEE ultrasound probes.

TD-12® high level disinfectant and TD 200® disinfectant 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® disinfectant:

High-level Disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-12®	3 minutes	38°C	1750 ppm peracetic acid

QwikCheck™ Chemical Indicators are used prior to the disinfection cycle to ensure that the disinfectant used is above the minimum recommended concentration (MRC) of 1750 ppm peracetic acid.

Comparative Table for Indications for Use

Element	Proposed Device	Predicate Device	Comparison
	TD 200 Disinfectant with TD-12 High-Level disinfectant with QwikCheck Chemical Indicator	TD 200 Disinfectant with TD-12 High-Level Disinfectant	
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)	Same
Indications for Use	The TD 200 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 disinfectant. 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	The TD 200 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 disinfectant. 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	Same

	<p>TD 200 disinfectant for high-level disinfection of TEE ultrasound probes.</p> <p>TD-12 high level disinfectant and TD 200 disinfectant is intended for use by qualified individuals trained in its use.</p> <p>TD-12 disinfectant should be used with the following contact conditions in TD 200 disinfectant: High-level Disinfectant TD-12 Time - 3 Minutes Temperature - 38°C Minimum Recommended Concentration (MRC) 1750 ppm Peracetic Acid</p> <p>QwikCheck Chemical Indicators are used prior to the disinfection cycle to ensure that the disinfectant used is above the minimum recommended concentration (MRC) of 1750ppm peracetic acid.</p>	<p>TD 200 disinfectant for high-level disinfection of TEE ultrasound probes.</p> <p>TD-12 high level disinfectant and TD 200 disinfectant is intended for use by qualified individuals trained in its use.</p> <p>TD-12 disinfectant should be used with the following contact conditions in TD 200 disinfectant: High-level Disinfectant TD-12 Time - 3 Minutes Temperature - 38°C Minimum Recommended Concentration (MRC) 1.75% Peracetic Acid</p>	
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Comparison of Proposed TD 200 Device to Primary Predicate TD 200 Device

Features	Proposed Device	Predicate Device	Comparison
	TD 200® Automated TEE Probe Disinfectant with TD-12® High Level Disinfectant with QwikCheck Chemical Indicator	TD 200® Automated TEE Probe Disinfectant with TD-12® High Level Disinfectant (K192228)	
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 disinfectant contact time, at least 180 seconds and disinfects at 38°C	Yes	Yes	Same
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 serial number, lot number of disinfectant, probe number, and operator number on output ticket	Yes	Yes	Same
Minimal footprint, secured to wall for stability	Yes	Yes	Same
Design			
Intended Use	Automated high-level disinfection of TEE probes	Automated high-level disinfection of TEE probes	Same
Manual Pre-cleaning	Yes	Yes	Same
Operating principles	Peracetic Acid high-level disinfection	Peracetic Acid high-level disinfection	Same
Process monitors	Digital display screen, printout	Digital display screen, printout	Same
Software/firmware control	Yes	Yes	Same
Performance claims	High-level disinfection	High-level disinfection	Same
Provides high-level disinfection for heat-sensitive TEE probes	Yes	Yes	Same
Uses PAA-based disinfectants	Yes	Yes	Same
Automated disinfection cycle	Yes	Yes	Same
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 Disinfectants for use with the device	Peracetic acid (TD-12)	Peracetic acid (TD-12)	Same
Disinfectant Minimum Recommended Concentration	1750 ppm Peracetic Acid	1.75% Peracetic Acid	Same
110 VAC	Yes	Yes	Same
Potable Water Inlet	Yes	Yes	Same
User hazard to vapor exposure controlled by vapor management system utilizing air circulation and filtration with no room air circulation required	Yes	Yes	Same
Use a chemical indicator	Yes	Yes	Same

Comparison of Proposed TD 12 Device to Primary Predicate TD 12 Device

Physical Properties	Proposed Device TD-12	Predicate Device TD-12 (K192228)	Comparison
Active Ingredients	0.30% peracetic acid	0.30% peracetic acid	Same
Inert Ingredients	99.7%	99.7%	Same
Water-Based Liquid	No	No	Same
pH Value	8.5 – 9.0	8.5 – 9.0	Same
Buffer System	Sodium Carbonate and Sulfamic Acid	Sodium Carbonate and Sulfamic Acid	Same
Minimum Recommended Concentration (MRC)	1750 ppm	1.75%	Same
Dilution Required	Yes	Yes	Same
Activation Required	Yes	Yes	Same
High-Level Disinfection Claim	Yes	Yes	Same
Sterilization Claim	No	No	Same
Maximum Re-Use Period	Single Use	Single Use	Same
PAA Test	Yes	Yes	Same

Strip Available			
Use in Automated Disinfector	Required	Required	Same
Manual Use	No	No	Same
Disinfectant Temperature Minimum	38°C	38°C	Same
Disinfection Time	3 Minutes	3 Minutes	Same

Comparative Table between QwikCheck Chemical Indicators

Element	QwikCheck Chemical Indicator (proposed device)	QwikCheck Chemical Indicator (device used in conjunction with K192228)	Comparison
Classification Name (CFR; Product code)	Sterilization Process Indicator (21 C.F.R. § 880.2800, product code JOJ)	Sterilization Process Indicator (21 C.F.R. § 880.2800, product code JOJ)	Same
Indications for Use for Chemical Indicator	QwikCheck Chemical Indicators are used prior to the disinfection cycle to ensure that the disinfectant used is above the minimum recommended concentration (MRC) of 1750ppm peracetic acid.	The QwikCheck™ Chemical Indicator is a qualitative chemical indicator dedicated for use in determining whether the concentration of peracetic acid, the active ingredient in CS Medical's TD-12 Solution, is above or below the established Minimum Recommended Concentration (MRC) according to the solution manufacturer.	Similar
Analyte	Peracetic acid in TD-12 Solution	Peracetic acid in TD-12 Solution	Same
Indicator Strip	0.2" x 0.2" test paper attached to a plastic handle	0.2" x 0.2" test paper attached to a plastic handle	Same
Indicator Agents	Starch and iodide	Starch and iodide	Same

Minimum Time of Color Change	30 seconds	30 seconds	Same
Results	A test pad which is similar in color to the FAIL color block indicates the solution is \leq 1750 ppm. If the color of the test pad is similar to the PASS block, the solution is $>$ 1750 ppm	A test pad which is similar in color to the FAIL color block indicates the solution is \leq 1750 ppm. If the color of the test pad is similar to the PASS block, the solution is $>$ 1750 ppm	Same

The only one difference between the subject and predicate devices is a change of supplier of the QwikCheck Chemical Indicator.

Summary of 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.

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 on materials.

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 38°C.

Performance Testing

TD-12 High Level Disinfectant 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 disinfectant. In all cases there was a measurably complete kill of microorganisms after TEE probe processing.

Clinical In-Use Testing

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

No clinical in-use testing was performed with the QwikCheck chemical indicators as no clinical in-use testing was performed with the predicate chemical indicators so this testing is not applicable.

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data the TD 200 Automated TEE Probe Disinfectant with TD-12 High Level Disinfectant with QwikCheck Chemical Indicators is as safe, as effective, and performs as well as or better than the legally marketed predicate device CS Medical TD 200 Automated TEE Probe Disinfectant with TD-12 High Level Disinfectant (K192228).