



Food and Drug Administration  
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May 30, 2017

CS Medical LLC  
Mr. Kendall Ashe  
Vice President  
2179 East Lyon Station Road  
Creedmoor, North Carolina 27522

Re: K160921

Trade/Device Name: CS Medical TD-100<sup>®</sup> Disinfector with TD-5<sup>®</sup> and TD-8<sup>®</sup> High Level  
Disinfectants

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic Ultrasonic Transducer

Regulatory Class: Class II

Product Code: PSW

Dated: October 3, 2016

Received: October 4, 2016

Dear Mr. Ashe:

This letter corrects our substantially equivalent letter of November 3, 2016.

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" (21 CFR 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  
-S

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

## Indications for Use

510(k) Number (if known)

K160921

Device Name

CS Medical TD-100® Disinfector with TD-5® and TD-8® High Level Disinfectant System

### Indications for Use (Describe)

The TD 100® disinfector is designed to provide high-level disinfection of Transesophageal (TEE) ultrasound 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® disinfectant is 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® high level disinfectant 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	Time	Temperature	Minimum Recommended Concentration
TD-5®	5 minutes	38°C – 40°C	1.7% glutaraldehyde

TD-8® disinfectant is 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-8® high level disinfectant and TD 100® disinfector system are intended for use by qualified individuals trained in its use.

TD-8® disinfectant should be used with the following contact conditions in TD 100® disinfector:

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

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 – K160921

### 510(k) Owner

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### Contact Person

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### Submission Prepared

November 3, 2016

<u>CS Medical Trade Name</u>	<u>Common Name</u>	<u>Classification Name</u>
TD 100® Disinfector with TD-5® and TD-8® High Level Disinfectants	TD 100 automated disinfector with TD-5 and TD-8 disinfectants	Diagnostic ultrasound transducer (21 CFR 892.1570, Primary Product Code ITX)

### Legally Marketed Predicate Devices

1. CS Medical TD 100® Transesophageal Probe Disinfector and TD-5 High-level Disinfectant (K051305) – Primary Predicate
2. Rapicide OPA-28® (K120306)
3. Metricide OPA Plus (K070627 as Opaciden Solution)
4. Cidex OPA (K030004)

## Description of the CS Medical TD 100<sup>®</sup> Disinfector with TD-5<sup>®</sup> and TD-8<sup>®</sup> High Level Disinfectants

The TD 100<sup>®</sup> disinfector provides high level disinfection of transesophageal (TEE) ultrasound probes when used according to the operating instructions, and when used with TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectants. The TD 100<sup>®</sup> disinfector is for use only with TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectants. The TD-5<sup>®</sup> and TD-8<sup>®</sup> disinfectants are for use only in the TD 100 disinfector. Thus, the TD 100<sup>®</sup> disinfector with TD-5<sup>®</sup> and TD-8<sup>®</sup> disinfectants represents 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 100<sup>®</sup> disinfector. A fresh, unopened bottle of TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectant is loaded into the TD 100<sup>®</sup> disinfector. The TD 100<sup>®</sup> disinfector heats the TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectant to 38°-40°C, soaks the TEE probe for at least five minutes, and then thoroughly rinses the disinfectant off the TEE probe before the cycle is complete. The TD 100<sup>®</sup> disinfector prints a verification report indicating a successful disinfection cycle and the time and average temperature during the disinfection. The TEE probe is then removed from the TD 100<sup>®</sup> disinfector and dried according to the TEE probe manufacturer's instructions. The TD 100<sup>®</sup> disinfector is ready for a new cycle immediately after the preceding cycle is completed. Because a fresh bottle of TD-5<sup>®</sup> or TD-8<sup>®</sup> 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

The TD 100<sup>®</sup> disinfector is designed to provide high-level disinfection of Transesophageal (TEE) probes. The system can use TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectants, which are designed to be used only with the TD 100<sup>®</sup> disinfector. The disinfectant bottles cannot be reused in the system.

TD-5<sup>®</sup> disinfectant is intended for use as single use high-level disinfectant to be used exclusively in the TD 100<sup>®</sup> disinfector for high-level disinfection of TEE ultrasound probes.

TD-5<sup>®</sup> high level disinfectant and TD 100<sup>®</sup> disinfector system are intended for use by qualified individuals trained in its use.

TD-5<sup>®</sup> disinfectant should be used with the following contact conditions in TD 100<sup>®</sup> disinfector:

High-level disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-5 <sup>®</sup>	5 minutes	38°– 40°C	1.7% glutaraldehyde

TD-8<sup>®</sup> disinfectant is intended for use as single use high-level disinfectant to be used exclusively in the TD 100<sup>®</sup> disinfectant for high-level disinfection of TEE ultrasound probes.

TD-8<sup>®</sup> high level disinfectant and TD 100<sup>®</sup> disinfectant system are intended for use by qualified individuals trained in its use.

TD-8<sup>®</sup> disinfectant should be used with the following contact conditions in TD 100<sup>®</sup> disinfectant:

High-level disinfectant	Time	Temperature	Minimum Recommended Concentration
TD-8 <sup>®</sup>	5 minutes	38°-- 40°C	0.3% ortho-phthalaldehyde

**Table C.1a: Comparative Table for TD 100<sup>®</sup>**

Element	Proposed Device TD 100 <sup>®</sup> Disinfectant with TD-5 <sup>®</sup> and TD-8 <sup>®</sup> High Level Disinfectants	Predicate Device TD 100 <sup>®</sup> Transesophageal Probe Disinfectant and TD-5 High-level Disinfectant (K051305)	Predicate Device Rapicide OPA-28 <sup>®</sup> (K120306)	Predicate Device Metricide OPA Plus (K070627 As Opaciden)	Predicate Device Cidex OPA (K030004)
Classification Name (CFR; Product code)	Diagnostic ultrasound transducer (21 CFR § 892.1570, Primary Product Code - ITX)	Diagnostic ultrasound transducer (21 CFR § 892.1570, Primary Product Code - ITX)	Liquid chemical germicide/high level disinfectant (21 CFR § 880.6885, Product Code MED)	Liquid chemical germicide/high level disinfectant (21 CFR § 880.6885, Product Code MED)	Liquid chemical germicide/high level disinfectant (21 CFR § 880.6885, Product Code MED)
Indications For Use	The TD 100 <sup>®</sup> disinfectant is designed to provide high-level disinfection of Transesophageal (TEE) probes. The system can use TD-5 <sup>®</sup> or TD-8 <sup>®</sup> disinfectants, which are designed to be used only with the TD 100 <sup>®</sup> disinfectant. The disinfectant bottles cannot be reused in the system. TD-5 <sup>®</sup> disinfectant is intended for use as single use high-level	The TD 100 <sup>®</sup> disinfectant is designed to provide high-level disinfection of Transesophageal (TEE) ultrasound probes. The system uses the TD-5 <sup>®</sup> disinfectant, which is designed to be used only with the TD 100. The disinfectant bottles cannot be reused in the system. TD-5 <sup>®</sup> is intended for	Rapicide OPA-28 is a high level disinfectant solution for reprocessing of heat sensitive semi critical medical devices for which sterilization is not suitable. Rapicide OPA-28 may be used at or above its minimum recommended concentration (MRC) of 0.35% OPA as determined by Rapicide OPA-28 test strips in	Metricide OPA Plus (K070627 as Opaciden) Solution is a high level disinfectant for reprocessing heat-sensitive medical devices for which sterilization is not suitable, and when used according to the Directions for Use. Metricide OPA Plus (K070627 as Opaciden) may be used or reused at or above its Minimum Recommended Concentration (MRC) of 0.3%, as determined by	CIDEX OPA Solution is intended for use as a high level disinfectant for reprocessing heat sensitive medical devices. CIDEX OPA Solution can be used in manual systems (trays and buckets) and automated endoscope reprocessors.

Element	Proposed Device TD 100 <sup>®</sup> Disinfector with TD-5 <sup>®</sup> and TD-8 <sup>®</sup> High Level Disinfectants	Predicate Device TD 100 <sup>®</sup> Transesophageal Probe Disinfector and TD-5 High- level Disinfectant (K051305)	Predicate Device Rapicide OPA-28 <sup>®</sup> (K120306)	Predicate Deice Metricide OPA Plus (K070627 As Opaciden)	Predicate Deice Cidex OPA (K030004)
	<p>disinfectant to be used exclusively in the TD 100<sup>®</sup> disinfector for high-level disinfection of TEE ultrasound probes.</p> <p>TD-5<sup>®</sup> high level disinfectant and TD 100<sup>®</sup> disinfector system are intended for use by qualified individuals trained in its use.</p> <p>TD-5<sup>®</sup> disinfectant should be used with the following contact conditions in TD 100<sup>®</sup> disinfector:</p> <p>High-level disinfectant TD-5<sup>®</sup></p> <p>Time 5 minutes</p> <p>Temperature 38° – 40°C</p> <p>Minimum Recommended Concentration 1.7% glutaraldehyde</p> <p>TD-8<sup>®</sup> disinfectant is intended for use as single use high-level disinfectant to be used exclusively in the TD 100<sup>®</sup> disinfector for high-level disinfection of TEE ultrasound probes.</p> <p>TD-8<sup>®</sup> high level disinfectant and TD 100<sup>®</sup> disinfector system are intended for use by qualified individuals trained in its use.</p>	<p>use as a single use high-level disinfectant to be used exclusively in the TD 100<sup>®</sup> for the high-level disinfection of TEE ultrasound probes.</p> <p>The TD-5<sup>®</sup> High Level Disinfectant and TD 100<sup>®</sup> disinfector system is intended for use by qualified individuals trained in its use.</p>	<p>manual device reprocessing with an immersion time of at least 10 minutes at a minimum temperature of 20°C for a reuse period not to exceed 28 days.</p> <p>Rapicide OPA-28 may also be used in compatible legally marketed automatic endoscope reprocessors at or above its MRC as determined by Rapicide OPA-28 test strips with an immersion time of at least 5 minutes at a minimum temperature of 25°C for a reuse period not to exceed 28 days.</p>	<p>Metricide OPA Plus (K070627 as Opaciden) OPA Reagent Strips, in manual reprocessing with an immersion time of at least 12 minutes at a minimum of 20° C (68° F), for a reuse period not to exceed 14 days.</p> <p>Metricide OPA Plus (K070627 as Opaciden) may also be used or reused in a legally marketed automatic endoscope reprocessor (that can be set to a minimum of 25° C), at or above its Minimum Recommended Concentration (MRC), as determined by Metricide OPA Plus (K070627 as Opaciden) OPA Reagent Strips, with an immersion time of at least 5 minutes at a minimum of 25° C (77° F), for a reuse period not to exceed 14 days.</p>	

Element	Proposed Device TD 100 <sup>®</sup> Disinfector with TD-5 <sup>®</sup> and TD-8 <sup>®</sup> High Level Disinfectants	Predicate Device TD 100 <sup>®</sup> Transesophageal Probe Disinfector and TD-5 High- level Disinfectant (K051305)	Predicate Device Rapicide OPA-28 <sup>®</sup> (K120306)	Predicate Deice Metricide OPA Plus (K070627 As Opaciden)	Predicate Deice Cidex OPA (K030004)
	<p>TD-8<sup>®</sup> disinfectant should be used with the following contact conditions in TD 100<sup>®</sup> disinfector:</p> <p>High-level disinfectant TD-8<sup>®</sup></p> <p>Time 5 minutes</p> <p>Temperature 38° – 40°C</p> <p>Minimum Recommended Concentration 0.3% ortho-phthalaldehyde</p>				
Instrumentation For Automation	<p>TD 100<sup>®</sup> with TD-5<sup>®</sup> and TD-8<sup>®</sup> disinfector is automated for single use with only TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectants. The user initiates automated cycle and receives disinfection verification ticket via touchpad. Software and user interface has been modified as compared to the predicate TD 100<sup>®</sup> (K051305) to facilitate choice of TD-5<sup>®</sup> or TD-8<sup>®</sup> disinfectants and minor updates. Other aspects of the instrumentation are identical to current TD 100<sup>®</sup> and TD-5<sup>®</sup> device.</p>	<p>TD 100<sup>®</sup> disinfector is automated for single use with only TD-5<sup>®</sup> disinfectant. The user initiates automated cycle and receives disinfection verification ticket via touchpad.</p>	<p>Rapicide OPA-28 is indicated for manual use and use with undesignated (legally marketed) automatic reprocessors that provide designated contact conditions.</p>	<p>Metricide OPA Plus (K070627 as Opaciden) is indicated for manual use and use with undesignated (legally marketed) automatic reprocessors that provide designated contact conditions.</p>	<p>Cidex OPA is indicated for manual use and use with undesignated (legally marketed) automatic reprocessors that provide designated contact conditions.</p>



**Table C.1b: Comparative Table for TD-8**

Physical Properties	TD-8®	TD-5®	Rapicide OPA-28	Metricide OPA Plus (As Opaciden)	Cidex OPA
510(k) Number	K160921	K051305	K120306	K070627 (As Opaciden)	K030004
Clearance Date	TBD	8/18/05	9/27/12	8/2/2007	2/27/2003
Active Ingredients	Ortho-phthalaldehyde 0.59%	Glutaraldehyde 2.65%	Ortho-phthalaldehyde 0.575%	Ortho-phthalaldehyde 0.6%	Ortho-phthalaldehyde 0.55%
Inert Ingredients	99.41%	97.35%	99.425%	99.4%	99.45%
Water-Based Liquid	Yes	Yes	Yes	Yes	Yes
pH Value	7.45 – 7.55	5.9 – 6.8	7.5 – 8.0	7.0-7.8	7.2-7.8
Buffer System	Phosphates	Phosphates	Not Published	Phosphates	Phosphates
Minimum Recommended Concentration (MRC)	0.3%	1.7%	0.35%	0.3%	0.3% (MEC)
Dilution Required	No	No	No	No	No
Activation Required	No	No	No	No	No
High-Level Disinfection Claim	Yes	Yes	Yes	Yes	Yes
Sterilization Claim	No	No	No	No	No
Maximum Re-Use Period	Single Use	Single Use	28 Days	14 Days	14 Days
OPA Test Strip Available	No	No	Yes	Yes	Yes
Use in Automated Disinfector	Required	Required	Optional	Optional	Optional
Manual Use	No	No	Optional	Optional	Optional
Reusable Devices	TEE Probes ONLY	TEE Probes ONLY	Endoscopes	Endoscopes	Endoscopes
Disinfectant Temperature Minimum	38°C	38°C	25°C	25°C	25°C
Disinfectant Temperature Maximum	40°C	40°C	No Limit	No Limit	No Limit
Disinfection Time	5 Minutes	5 Minutes	5 Minutes	5 Minutes	5 Minutes

**Table C.1c: Comparative Table for TD-8, TD-5**

Test	Organism	TD-8 (Appendix 5)	TD-5	Rapicide OPA-28 (Appendix A1.7)	Metricide OPA Plus (K070627 as Opaciden) (Appendix 9)	Cidex OPA (Appendix 9)
Sporicidal	Bacillus subtilis	32.0 hrs at 37°C	10 min at 21°C	32 hrs at 25°C	32 hrs at 25°C	32 hrs at 25°C
Sporicidal	Clostridium sporogenes	32.0 hrs at 37°C	10 min at 21°C	32 hrs at 25°C	Not performed	Not performed
Tuberculocidal	Mycobacterium terrae	5.0 min at 37°C	< 1 min at 37°	Not performed	5 min at 25°C	5 min at 25°C
Bactericidal	Staphylococcus aureus	5.0 min at 37°C	10 min at 25°C	5 min at 25°C	5 min at 25°C	5 min at 25°C
Bactericidal	Salmonella enterica	5.0 min at 37°C	10 min at 25°C	5 min at 25°C	5 min at 25°C	5 min at 25°C
Bactericidal	Pseudomonas aeruginosa	5.0 min at 37°C	10 min at 25°C	5 min at 25C	5 min at 25°C	5 min at 25°C
Fungicidal	Trichophyton mentagrophytes	5.0 min at 37°C	10 min at 25°C	5 min at 25°C	5 min at 25°C	5 min at 25°C
Virucidal	Poliovirus Type 1	5.0 min at 37°C	5 min at 25°C (type 2)	5 min at 25°C	5 min at 25°C	5 min at 25°C
Virucidal	Herpes Simplex Virus Type 1	5.0 min at 25°C	5 min at 25°C	5 min at 25°C	5 min at 25°C	5 min at 25°C
Virucidal	Human Influenza Virus A	5.0 min at 25°C	Not performed	Not performed	5 min at 25°C	5 min at 25°C
Virucidal	Adenovirus Type 1	5.0 min at 25°C	Not performed	Not performed	5 min at 25°C*	5 min at 25°C*
Simulated Use	Mycobacterium terrae	5.0 min at 37°C	5 min at 37°C	5 min at 25°C	5 min at 25°C	5 min at 25°C
Clinical In-Use	Wild-type from patients	5.0 min at 37°C	5 min at 37°C	5 min at 25°C	5 min at 25°C	5 min at 25°C

\* Adenovirus Type 2 tested

### Clinical In-Use Testing

After routine clinical use, soiled TEE probes were subjected to disinfection in the TD 100® disinfectant with TD-8® disinfectant with standard operating parameters. In all cases there was a measurably complete kill of microorganisms after TEE probe processing.

### Biocompatibility

Under the conditions of the study, TD-8<sup>®</sup> is not a sensitizer, nor an irritant and is non-cytotoxic.

### Material Compatibility

The materials used to construct the TD 100<sup>®</sup> disinfectant were exposed to TD-8<sup>®</sup> disinfectant for a pre-determined period of time. There were no observable effects from exposure to TD-8<sup>®</sup> disinfectants on materials.

### Compatibility Testing with TEE Probes

The TD 100<sup>®</sup> Disinfectant, TD-5<sup>®</sup> and TD-8<sup>®</sup> 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 model 6VT-D TEE probes. Residues from these probes exhibited a slight cytotoxic effect per ISO 10993-5 and did not have visible probe deterioration.

### Stability

TD-8<sup>®</sup> High Level Disinfectant has been tested and shown to be stable for a shelf life of 12 months. The concentration of the disinfectant at the end of 12 months of testing is well above the 0.3% minimum recommended concentration.

### Conclusions

It is the conclusion of the CS Medical Scientific and Management team that the preponderance of evidence supports the designation of the TD 100<sup>®</sup> Disinfectant with TD-5<sup>®</sup> and TD-8<sup>®</sup> High Level Disinfectants under consideration here (K160921) as substantially equivalent to the predicate TD 100<sup>®</sup> Disinfectant with TD-5<sup>®</sup>, Rapicide OPA-28, Metrex Plus OPA (K070627 as Opaciden) and Cidex OPA.