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

CS Medical LLC
Mr. Ben Chemelli
Vice President
3248 Lake Woodard Drive
Raleigh, North Carolina 27604

Re: K051305
Trade/Device Name: CS Medical TD-100 Transesophageal Probe Disinfector, Model
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: PSW
Dated: July 29, 2005
Received: August 1, 2005

Dear Mr. Chemelli:

This letter corrects our substantially equivalent letter of August 18, 2005.

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

Indications for Use

510(k) Number: K051305

Device Name: TD-5 High Level Disinfectant and TD-100 Transesophageal Probe Disinfector

Indications For Use:

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 the high-level disinfection of TEE ultrasound probes.

TD-5 High Level Disinfectant should be used with the following contact conditions:

	Time	Temperature	Minimum Recommended Concentration
High Level Disinfection	5 Minutes	38-40°C	1.7%

The TD-5 High Level Disinfectant and TD-100 disinfector system is intended for use by qualified individuals trained in its use.

Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K051305

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12 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Contact:

CS Medical L.L.C.
3248 Lake Woodard Drive
Raleigh, NC 27604

Contact Person: Ben Chemelli

Date Prepared: May 16, 2005

Device Name:

Trade name:
CS Medical TD-100 Transesophageal Probe Disinfector
CS Medical TD-5 High-level Disinfectant

Classification:
Endoscope and Accessories. 21 C.F.R. § 876.1500.
High Level Liquid Chemical Disinfectant. 21 C.F.R. § 880.6885.

Predicate Devices:

(1) Medivators DSD™ Disinfector For Flexible Endoscopes (K914145)
(2) Wavicide-01 (K914749)
(3) Medivators Rapicide™ 5 Minute High-Level Disinfectant (K993042)

The DSD system uses a High-level Disinfectant to reprocess reusable flexible endoscopes. It controls the environmental conditions (for example contact time with the disinfectant, temperature of the disinfectant and rinsing) necessary for effective disinfection of the device being processed.

Device Description:

The TD-100 disinfector provides high-level disinfection of transesophageal (TEE) ultrasound probes when used according to the operating instructions, and when used with TD-5 disinfectant. Each soiled TEE probe is pre-cleaned manually before insertion into the TD-100 disinfector. A fresh, unopened bottle of TD-5 disinfectant is loaded into the TD-100 disinfector. The TD-100 disinfector heats the TD-5 disinfectant to 38-40C, soaks the TEE probe at least five-minutes, and then thoroughly rinses the disinfectant off the TEE probe before the cycle is complete. The TEE probe is then removed from the TD-100 disinfector and dried according to the TEE probe manufacturer's instructions. The TD-100 disinfector is ready for a new cycle immediately after the preceding cycle is completed. Because a fresh bottle of TD-5 disinfectant is used with each cycle no monitoring of the disinfectant's potency required, nor is there any requirement for daily testing of the disinfectant solution.

Intended Use:

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 the 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.

Efficacy Testing:

Simulated Use Testing: The High-level Disinfection capabilities of the TD-100 disinfector and TD-5 High-level Disinfectant were evaluated for efficacy in a simulated use environment. In all cases a 6-Log_{10} reduction of *M. terrae* was achieved when disinfecting TEE probes that were dosed with artificial soil containing *M. terrae*.

In Use Testing: TEE Probes used in a clinical setting were examined. The probes were bioburden post cleaning and a new population of probes was examined for bioburden after disinfection. In all cases, there was a complete kill of microbes after disinfection.

Biocompatibility:

Transesophageal probes processed in the TD-100 using TD-5 were evaluated for disinfectant residue. The analysis indicates that the level of residue on the TEE probes in not likely to have toxic effects on humans.

Material Compatibility:

The materials used to construct the TD-100 were exposed to TD-5 High-level Disinfectant for an extended period of time. There were no observable effects from exposure to TD-5.

Stability:

TD-5 High Level disinfectant has been tested and shown to be stable for a shelf life of one-year. The concentration of the disinfectant at the end of 18 months of testing is well about the 1.7% minimum recommended concentration.

Conclusion:

The information and data presented demonstrate substantial equivalence to the predicate devices. The TD-100 and TD-5 are substantially equivalent to other legally marketed devices.