DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K182891

Device Name

TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants

Indications for Use *(Describe)*

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	38º-40ºC	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	38º-40ºC	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.

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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