June 7, 2023

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

Re: K230381
Trade/Device Name: Ethos Automated Ultrasound Probe Cleaner Disinfector with AquaCide Cleaner/High-Level Disinfectant and QwikCheck Chemical Indicator
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: PSW
Dated: May 12, 2023
Received: May 12, 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 (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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230381

Device Name
Ethos Automated Ultrasound Probe Cleaner Disinfector with AquaCide Cleaner/High-Level Disinfectant and QwikCheck Chemical Indicator

Indications for Use *(Describe)*
The Ethos automated ultrasound probe cleaner disinfector is designed to provide cleaning and high-level disinfection of surface and endocavity ultrasound probes. The system uses AquaCide cleaner/disinfectant, which is designed to be used only with the Ethos automated cleaner disinfector. The disinfectant bottles cannot be reused in the system.

AquaCide cleaner/disinfectant is intended for use as a single use cleaner and high-level disinfectant, used exclusively in the Ethos automated cleaner disinfector for cleaning and high-level disinfection of surface and endocavity ultrasound probes.

AquaCide cleaner/disinfectant should be used with the following contact conditions in the Ethos automated cleaner disinfector:

High-level Disinfectant	Time	Temperature	Minimum Recommended Concentration
AquaCide	3 minutes	47oC	1750 ppm peracetic acid

The QwikCheck Chemical Indicator is for use in Ethos to determine whether the concentration of peracetic acid, the active ingredient in AquaCide, is above or below the Minimum Recommended Concentration (MRC) of 1750 ppm.

The Ethos cleaner disinfector with AquaCide and QwikCheck 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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510(K) SUMMARY - K230381

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Submission Prepared
6-June-2023

CS Medical Trade Name	Common Name	Classification Name
Ethos Automated Ultrasound Probe Cleaner Disinfector with AquaCide Cleaner/High-Level Disinfectant and QwikCheck Chemical Indicator	High level disinfection reprocessing instrument for ultrasonic transducers, liquid.	Diagnostic Ultrasound Transducer (21 CFR 892.1570, Product Code PSW)

Legally Marketed Predicate Devices

TEEClean Automated TEE Probe Cleaner Disinfector with TEEZyme and TD-5 or TD-8 (K182891) – Primary Predicate Device

Reference Device

TD 200 Automated TEE Probe Disinfector with TD-12 and QwikCheck (K192228) – Reference Device

Description of the CS Medical Ethos Automated Ultrasound Probe Cleaner Disinfector with AquaCide Cleaner/High-Level Disinfectant and QwikCheck Chemical Indicator

The Ethos cleaner disinfector provides cleaning and high-level disinfection of surface and endocavity ultrasound probes when used according to the operating instructions and when used with AquaCide cleaner/disinfectant. The Ethos cleaner disinfector is for use only with AquaCide cleaner/disinfectant. The AquaCide cleaner/disinfectant is for use only in the Ethos cleaner disinfector. Thus, the Ethos cleaner disinfector, AquaCide cleaner/disinfectant represent a dedicated system. Each soiled ultrasound probe has the condom/cover removed and is bedside cleaned according to the ultrasound probe manufacturer's instructions before insertion into the Ethos cleaner disinfector. If a

condom/cover is not used the user must manually clean the probe. A fresh, unopened bottle of granular PAA AquaCide cleaner/disinfectant is loaded into the Ethos. The Ethos brings in water, mixes and heats the AquaCide solution to a minimum of 47°. While that is occurring, the Ethos brings in water and the ultrasound probe is pre-rinsed. After temperature is achieved and MRC is confirmed, the Ethos bring the AquaCide solution to the probe and cleans and disinfects the ultrasound probe for at least three minutes. Then the Ethos thoroughly rinses the AquaCide off the ultrasound probe before the cycle is complete. The ultrasound probe is then removed from the Ethos and dried according to the ultrasound probe manufacturer's instructions. The Ethos is ready for a new cycle immediately after the preceding cycle is completed. The Ethos cleaner disinfector incorporates a method for validating the PAA solution through an automatic chemical indicator to ensure each dose of PAA is at or above the MRC. The Ethos cleaner disinfector prints a verification report indicating a successful cleaning and disinfection cycles as well as the time and the average temperature during the cleaning/disinfection. The ultrasound probe is then removed from the Ethos cleaner disinfector and dried according to the ultrasound probe manufacturer's instructions. The Ethos cleaner disinfector is ready for a new cycle immediately after the preceding cycle is completed.

Indications for Use Statement:

The Ethos automated ultrasound probe cleaner disinfector is designed to provide cleaning and high-level disinfection of surface and endocavity ultrasound probes. The system uses AquaCide cleaner/disinfectant, which is designed to be used only with the Ethos automated cleaner disinfector. The disinfectant bottles cannot be reused in the system.

AquaCide cleaner/disinfectant is intended for use as a single use cleaner and high-level disinfectant, used exclusively in the Ethos automated cleaner disinfector for cleaning and high-level disinfection of surface and endocavity ultrasound probes.

AquaCide cleaner/disinfectant should be used with the following contact conditions in the Ethos automated cleaner disinfector:

High-level Disinfectant	Time	Temperature	Minimum Recommended Concentration
AquaCide	3 minutes	47°C	1750 ppm peracetic acid

The QwikCheck Chemical Indicator is for use in Ethos to determine whether the concentration of peracetic acid, the active ingredient in AquaCide, is above or below the Minimum Recommended Concentration (MRC) of 1750 ppm.

The Ethos cleaner disinfector with AquaCide and QwikCheck are intended for use by qualified individuals trained in its use.

Comparison of Proposed Device to Reference Device and Primary Predicate Device

Element	**Proposed Device** CS Medical Ethos Automated Ultrasound Probe Cleaner Disinfector with AquaCide Cleaner/High-Level Disinfectant and QwikCheck Chemical Indicator (K230381)	**Primary Predicate Device** TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants (K182891)	**Reference Device** TD 200® Transesophageal Probe Disinfector and TD-12 High-level Disinfectant (K192228)	**Comparison**
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)	Diagnostic ultrasonic transducer (21 C.F.R. § 892.1570, Product Code PSW)	Proposed and primary predicate same classification
Indications for Use	The Ethos automated ultrasound probe cleaner disinfector is designed to provide cleaning and high-level disinfection of surface and endocavity ultrasound probes. The system uses AquaCide cleaner/disinfectant, which is designed to be used only with the Ethos automated cleaner disinfector. The disinfectant bottles cannot be reused in the system. AquaCide cleaner/disinfectant is intended for use as a single use cleaner and high-level disinfectant, used exclusively in the Ethos automated cleaner disinfector for cleaning and high-level disinfection of surface and endocavity ultrasound	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	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	Proposed device and primary predicate similar indications for use, reference device provides same disinfectant

	probes. AquaCide cleaner/disinfectant should be used with the following contact conditions in the Ethos automated cleaner disinfector: High-level Disinfectant AquaCide Time 3 minutes Temperature 47ºC Minimum Recommended Concentration 1750 ppm peracetic acid The QwikCheck Chemical Indicator is for use in Ethos to determine whether the concentration of peracetic acid, the active ingredient in AquaCide, is above or below the Minimum Recommended Concentration (MRC) of 1750 ppm. The Ethos cleaner disinfector with AquaCide and QwikCheck are intended for use by qualified individuals trained in its use.	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 TD-5 Time - 5 minutes Temperature - 38° - 40°C Minimum Recommended Concentration 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 TD-8 Time - 5 minutes Temperature - 38° - 40°C Minimum Recommended Concentration 0.3% ortho-phthalaldehyde TEEZyme enzymatic cleaner, TD-5 and TD-8 high level disinfectant, and	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 38ºC Minimum Recommended Concentration 1750 ppm peracetic acid	

		TEEClean automated cleaner disinfector system are intended for use by qualified individuals trained in its use.		
Instrumentation For Automation	Ethos® with AquaCide® disinfector is automated for single use with only AquaCide cleaner disinfectant. The user initiates the automated cleaning and disinfection cycles via touchpad and receives cleaning and disinfection verification ticket and data is stored electronically.	TEEClean® with TEEZyme® enzymatic cleaner and TD-5® or TD-8® disinfectors is automated for single use with only TD-5® or TD-8® disinfectants. The user initiates the automated cleaning and disinfection cycles via touchpad and receives cleaning and disinfection verification ticket and data is stored electronically.	TD 200® with TD-12® disinfector is automated for single use with only TD-12® disinfectant. The user initiates the automated cycle via touchpad and receives disinfection verification ticket.	Proposed device and primary predicate device similar, reference device provides same disinfectant

Comparison of Operational Principles

Ethos (K230381)	**TEEClean (K182891)**	**TD 200 (K192228)**
The Ethos cleaner disinfector provides high-level disinfection of surface and endocavity ultrasound probes when used according to the operating instructions, and when used with AquaCide cleaner disinfectant. Each soiled ultrasound probe has the condom/cover removed and pre-cleaned before insertion into the Ethos. A fresh, unopened bottle of AquaCide cleaner disinfectant is loaded into the Ethos. The Ethos heats the AquaCide cleaner disinfectant to the correct temperature and MRC while spraying the ultrasound probe with water. After MRC is confirmed the AquaCide solution is sprayed in the ultrasound probe at the correct temperature and time for disinfection. Then the Ethos thoroughly rinses the AquaCide off the	The TEEClean cleaner disinfector provides high-level disinfection of transesophageal (TEE) ultrasound probes when used according to the operating instructions, and when used with TEEZyme enzymatic cleaner and either TD-5 or TD-8 disinfectant. Each soiled ultrasound probe is pre-cleaned manually before insertion into the TEEClean cleaner disinfector. A fresh, unopened bottle of TD-5 or TD-8 disinfectant is loaded into the TEEClean cleaner disinfector. The TEEClean cleaner disinfector heats the TEEZyme enzymatic cleaner to the correct temperature, soaks the ultrasound probe, and then thoroughly rinses the enzymatic cleaner off the ultrasound probe before the cycle is complete. The TEEClean cleaner disinfector then heats the TD5 or TD-8 disinfectant to the	The TD 200 disinfector provides high-level disinfection of transesophageal (TEE) ultrasound probes when used according to the operating instructions, and when used with TD-12 disinfectant. Each soiled ultrasound probe is pre-cleaned and manually cleaned 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 the correct temperature, soaks the ultrasound probe, and then thoroughly rinses the disinfectant off the ultrasound probe before the

ultrasound probe before the cycle is complete. The ultrasound probe is then removed from the Ethos and dried according to the ultrasound probe manufacturer's instructions. The Ethos cleaner disinfector is ready for a new cycle immediately after the preceding cycle is completed. A fresh bottle of AquaCide cleaner disinfectant is used with each cycle and mixed inside the Ethos, monitoring of the disinfectant's potency required at the MRC of 1750 ppm and QwikCheck is used. Due to the disinfectant cycling through the entire AquaCide system, the Ethos disinfects itself by the conclusion of the cycle.	correct temperature, soaks the ultrasound probe, and then thoroughly rinses the disinfectant off the ultrasound probe before the cycle is complete. The ultrasound probe is then removed from the TEEClean cleaner disinfector and dried according to the ultrasound probe manufacturer's instructions. The TEEClean cleaner disinfector is ready for a new cycle immediately after the preceding cycle is completed. Because a fresh bottle of TD-5 or TD-8 disinfectant is used with each disinfection cycle, no monitoring of the disinfectant's potency is required, nor is there any requirement for daily testing of the disinfectant solution. Due to the disinfectant cycling through entire TEEClean system, the TEEClean disinfects itself at the conclusion of the disinfection cycle.	cycle is complete. The ultrasound 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 fresh bottle of TD-12 disinfectant is used with each cycle and mixed inside the TD 200 monitoring of the disinfectant's potency required at the MRC of 1750 ppm and QwikCheck is used. Due to the disinfectant cycling through the entire TD 200 system, the TD 200 disinfects itself by the conclusion of the disinfection cycle.

Comparison of Critical Design Features, Process Monitors, and Process Parameters

Characteristic	**Ethos Automated Ultrasound Probe Cleaner Disinfector with AquaCide and QwikCheck system**	**TEEClean Automated TEE Probe Cleaner Disinfector with TEEZyme Enzymatic Cleaner and TD-5 or TD-8 High-Level Disinfectants system**	**TD 200/TD-12 disinfector/disinfectant system**	**Compare**
510(k) number	K230381	K182891	K192228	
Intended Use	Automated cleaning and high-level disinfection of surface and endocavity ultrasound probes	Automated cleaning and high-level disinfection of TEE ultrasound probes	Automated high-level disinfection of TEE ultrasound probes	Similar
Cleaner for use with the device	AquaCide (Peracetic Acid) 1750 ppm	TEEZyme < 1% Subtilisins	N/A	Similar
Dedicated Disinfectants for use with the device	AquaCide (Peracetic Acid)	TD-5 (Glutaraldehyde); TD-8 (Ortho-phthalaldehyde)	TD-12 (Peracetic Acid)	Similar
Disinfectant Minimum Recommended Concentration	AquaCide (Peracetic Acid) 1750 ppm	TD-5 (1.7% Glutaraldehyde); TD-8 (0.3% Ortho-phthalaldehyde)	TD-12 (Peracetic Acid) 1750 ppm	Similar
Disinfectant Buffer System	Sodium Carbonate and Sulfamic Acid	Phosphates	Sodium Carbonate and Sulfamic Acid	Similar

Disinfectant pH	8.5 – 9.0	7.45 – 7.55	8.5 – 9.0	Similar
Operating principles	Peracetic acid sterilization	Aldehyde sterilization	Peracetic acid sterilization	Similar
Process monitors	Digital display screen, printout	Digital display screen, printout	Digital display screen, printout	Same
Process parameters	**Cleaning:** 7 min contact 38 - 54ºC **Disinfection:** 3 min contact at least 47ºC.	**Cleaning:** 3 min contact at least 45ºC. **Disinfection:** 5 min contact at 38 – 40°C.	**Cleaning:** N/A **Disinfection:** 3 min contact at least 38ºC.	Similar
Software/firmware control	Yes	Yes	Yes	Same
Performance claims	Cleaning and High-level disinfection	Cleaning and High-level disinfection	High-level disinfection	Same
Provides high-level disinfection for heat-sensitive ultrasound probes	Yes	Yes	Yes	Same
Uses cleaner	Yes	Yes	No	Same
Uses peracetic acid based disinfectant	Yes	No	Yes	Similar
Uses aldehyde based disinfectants	No	Yes	No	Similar
Single-use disinfectants only i.e. no open bottle shelf life of disinfectant	Yes	Yes	Yes	Same
Single-use disinfectants unopened shelf life	18 months	12 months	18 months	Similar
Biocompatibility – skin irritation passing results	Yes	Yes	Yes	Same
Biocompatibility – sensitization passing results	Yes	Yes	Yes	Same
Biocompatibility – cytotoxicity passing results	Yes	Yes	Yes	Same
Toxicology assessment passing results	Yes	Yes	Yes	Same
Automated disinfection cycle	Yes	Yes	Yes	Same
Uses 5nm water filter for rinse water	Yes	Yes	No	Same
Disinfection process user control via software functions with success/failure print out	Yes	Yes	Yes	Same
User hazard to disinfectant contact reduced by	Yes	Yes	Yes	Same

bottle loading system				
User hazard to vapor exposure controlled by vapor management system utilizing air circulation and filtration with no room air circulation required	Yes	Yes	Yes	Same

Summary of Non-Clinical Studies

Title	**Purpose**	**Source & Acceptance Criteria**	**Result**
Biocompatibility Skin Irritation Test	To ensure contact with a reprocessed device will not cause skin irritation to patients	ISO 10993-10, under conditions of the study the device extract can be a slight irritant	Slight irritant
Biocompatibility Sensitization Test	To ensure contact with a reprocessed device will not cause skin sensitization to patients	ISO 10993-10, under conditions of the study the device extract can be a slight sensitizing	Non-sensitizing
Biocompatibility Cytotoxicity Test	To ensure contact with a reprocessed device will not cause cellular damage to patients	ISO 10993-5, under conditions of the study, device extract is not cytotoxic	Not cytotoxic
Toxicology Assessment	To ensure there was no other toxicological risks	FDA Submissions for Liquid Chemical Sterilants/High Level Disinfectants, evidence/ justifications provided device is non-toxic	Low risk of Toxic
Bacillus subtilis Bench Test	To ensure AquaCide has sporicidal efficacy for a high-level disinfectant	(AOAC) Official Method 966.04 for 5.0 hrs at 45°C have no growth	No growth
Clostridium sporogenes Bench Test	To ensure AquaCide has sporicidal efficacy for a high-level disinfectant	(AOAC) Official Method 966.04 for 5.0 hrs at 45°C have no growth	No growth
Mycobacterium terrae Bench Test	To ensure AquaCide has tuberculocidal efficacy for a high-level disinfectant	(AOAC) Official Method 965.12 for 3.0 mins at 45°C have at least 6log reduction	No growth
Staphylococcus aureus Bench Test	To ensure AquaCide has bactericidal efficacy for a high-level disinfectant	(AOAC) Official Method 955.15 for 3.0 mins at 45°C have at least 6log reduction	No growth
Salmonella enterica Bench Test	To ensure AquaCide has bactericidal efficacy for a high-level disinfectant	(AOAC) Official Method 955.14 for 3.0 mins at 45°C have at least 6log reduction	No growth
Pseudomonas aeruginosa Bench Test	To ensure AquaCide has bactericidal efficacy for a high-level disinfectant	(AOAC) Official Method 964.02 for 3.0 mins at 45°C have at least 6log reduction	No growth

Trichophyton interdigitale Bench Test	To ensure AquaCide has fungicidal efficacy for a high-level disinfectant	(AOAC) Official Method 955.17 for 3.0 mins at 45°C have at least 6log reduction	No growth
Herpes Simplex Virus Type 1 Bench Test	To ensure AquaCide has virucidal efficacy for a high-level disinfectant	ASTM E1053-20 for 3.0 mins at 45°C have greater than 6log reduction	Greater than 6log reduction
Human Influenza Virus A (H1N1) Bench Test	To ensure AquaCide has virucidal efficacy for a high-level disinfectant	ASTM E1053-20 for 3.0 mins at 45°C have greater than 6log reduction	Greater than 6log reduction
Adenovirus Type 1 Bench Test	To ensure AquaCide has virucidal efficacy for a high-level disinfectant	ASTM E1053-20 for 3.0 mins at 45°C have greater than 6log reduction	Greater than 6log reduction
Mycobacterium Terrae Simulated Use Test	To ensure when inoculated with the most robust organism, in the most challenging places on probes, in worst case conditions, the Ethos and AquaCide still perform high-level disinfection	Performed in Ethos per FDA Submissions for Liquid Chemical Sterilants/High Level Disinfectants for 3.0 mins at 45°C have greater than 6log reduction for all probes and all lots	All lots and all probes had greater than a 6log reduction
AquaCide Storage Stability Test	To ensure that at the end of the 18 month shelf life time the AquaCide can still meet specifications for high-level disinfection	FDA Submissions for Liquid Chemical Sterilants/High Level Disinfectants solubilized to meet MRC of 1750 ppm PAA at 18 months	18 month shelf life

Clinical In-Use Testing

After routine use, soiled surface and endocavity probes were subjected to cleaning and disinfection in the Ethos® cleaner disinfector with AquaCide® and QwikCheck® under standard operating parameters. In all cases there was a measurable complete kill of microorganisms after ultrasound probe processing.

Conclusion

Based on the intended use, technological characteristics, non-clinical performance data, and clinical in-use testing, Ethos® Automated Ultrasound Probe Cleaner Disinfector with AquaCide® Cleaner/High-Level Disinfectant and QwikCheck® Chemical Indicator (K230381) is as safe, as effective, and performs as well as or better than the legally marketed predicate device TEEClean® Automated TEE Probe Cleaner Disinfector with TEEZyme® Cleaner and TD-5® or TD-8® High-Level Disinfectants (K182891).