DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22,2014

Advanced Sterilization Products
Mr. Reuben Lawson
Sr. Manager, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K140977
Trade/Device Name: EVOTECH® ECR Endoscope Cleaner & Reprocessor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and Accessories
Regulatory Class: II
Product Code: FEB
Dated: November 24, 2014
Received: November 25, 2014

Dear Mr. Lawson:

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" (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 yours,

Erin I. Keith, M.S.
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): K140977

Device Name: **EVOTECH® ECR Endoscope Cleaner and Reprocessor**

The EVOTECH® ECR Endoscope Cleaner and Reprocessor, a washer/disinfector, is indicated for use with high-level disinfectant CIDEX® OPA Concentrate and an enzymatic detergent (CIDEZYME GI) to achieve cleaning and high level disinfection of heat sensitive (>60 0C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH® ECR System when selecting those cycles that contain a wash stage. (Manual cleaning of medical devices (endoscopes) is required when selecting the Disinfect only or Disinfect/Alcohol Flush Cycle.)

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

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products, Division of Ethicon, Inc.
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33 Technology Drive
Irvine, CA 92618

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SUMMARY DATE
December 18, 2014

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Trade Name:	EVOTECH® ECR Endoscope Cleaner & Reprocessor
Common/Usual Name:	Endoscope Cleaner & Reprocessor
Classification Name:	Endoscope & Accessories (21 CFR 876.1500, Product Code FEB)
Product Classification:	Class II

2. PREDICATE DEVICES

- EVOTECH® Integrated Washer Disinfector (K082392, cleared November 13, 2008)

3. DESCRIPTION OF DEVICE

The EVOTECH® ECR Endoscope Cleaner & Reprocessor is a two-basin washer/disinfector utilizing an enzymatic detergent and a concentrated high-level disinfectant, CIDEX OPA Concentrate Solution. Both the detergent and high-level disinfectant are diluted in the system to in-use concentrations. The EVOTECH® ECR Endoscope Cleaner & Reprocessor is capable of cleaning endoscopes that have not been manually cleaned prior to placing in the system.

Endoscopes that have been qualified for processing in the EVOTECH® ECR Endoscope Cleaner & Reprocessor must go through manual bedside pre-cleaning according to SGNA and facility guidelines prior to being placed in the EVOTECH® ECR Endoscope Cleaner & Reprocessor for automated cleaning and/or high level disinfection. If automatic cleaning is not available or desired for the device by the user, the endoscope must also be manually cleaned by the user prior to being placed in the EVOTECH® ECR Endoscope Cleaner & Reprocessor.

After the endoscopes are connected to the EVOTECH® ECR Endoscope Cleaner & Reprocessor, the detergent is sprayed onto the surface of the device, and pumped through the lumens of the device, at sufficient pressure levels to remove any soil present on or in the device.

The disinfectant is then mixed with incoming water, which is monitored to ensure that the water temperature is then sprayed onto the surface of the device, and pumped through the lumens of the device, at sufficient time and temperature to achieve high level disinfection of any microorganisms. The temperature is monitored to ensure operating parameters of 50°C are met. A sample of the diluted CIDEX OPA Concentrate solution is extracted to ensure minimum effective concentration levels have been achieved. Following disinfection, the endoscopes are rinsed by the machine and air pumped through the lumens to facilitate drying of the endoscope. If selected by the user, an alcohol flush cycle may also be run to facilitate drying of the endoscope. The endoscope may then be removed, dried and used. The onboard printer generates a cycle printout summarizing the cycle results for the user's records.

The machine has built in safety features which cancel the cycle and notify the user if parameters are not met. These notifications, their causes, and next steps for the user, are defined in the EVOTECH® ECR Endoscope Cleaner & Reprocessor User Guide.

4. INTENDED USE

The EVOTECH® ECR Endoscope Cleaner & Reprocessor is designed to automatically clean and high-level disinfect flexible, submersible video or fiber-optic endoscopes. High-level disinfection requires that the system be used with CIDEX® OPA Concentrate Solution

5. INDICATIONS FOR USE

The EVOTECH® ECR Endoscope Cleaner and Reprocessor, a washer/disinfector, is indicated for use with high-level disinfectant CIDEX® OPA Concentrate and an enzymatic detergent (CIDEZYME GI) to achieve cleaning and high level disinfection of heat sensitive (>60 0C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH® ECR Endoscope Cleaner & Reprocessor when selecting those cycles that contain a wash

stage. (Manual cleaning of medical devices (endoscopes) is required when selecting the Disinfect only or Disinfect/Alcohol Flush Cycle.)

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The EVOTECH® ECR Endoscope Cleaner & Reprocessor that is this subject of this submission is the same model as the predicate cleared in K082392. The comparison between the predicate device and the EVOTECH® ECR Endoscope Cleaner & Reprocessor shows the device to meet the definition of substantially equivalence because:

- the devices have the same intended use
- and the same technological characteristics

Feature	**Predicate Device** **EVOTECH® ECR Endoscope Cleaner and Reprocessor**	**New Device** **EVOTECH® ECR Endoscope Cleaner and Reprocessor**
Intended Use	The EVOTECH® ECR Endoscope Cleaner and Reprocessor is intended for use as a washer / disinfector for cleaning and high level disinfection of flexible endoscopes that do not contact normally sterile areas of the body.	Same as Predicate Device
Indications for Use	The EVOTECH® ECR Endoscope Cleaner and Reprocessor, a washer/disinfector, indicated is for use with high-level disinfectant CIDEX® OPA Concentrate and an enzymatic detergent (CIDEZYME GI) to achieve cleaning and high level disinfection of heat sensitive (>60 0C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH System when selecting those cycles that contain a wash stage. (Manual cleaning of medical devices (endoscopes) is required when selecting the Disinfect only or Disinfect/Alcohol Flush Cycle.)	Same as Predicate Device
Disinfectant Used	CIDEX OPA Concentrate Solution (Single Use)	Same as Predicate Device
Identification of materials that come into contact with fluid pathways	Endoscopes and materials comprising the EVOTECH® ECR Endoscope Cleaner and Reprocessor: powder coated aluminum glass, stainless steel, polyethylene, Neoprene, polypropylene, polyamide, Ultem, polycarbonate, polypropylene, CIDEX OPA Concentrate (in-use solution)	Same as Predicate Device
Process Monitors	In line optical monitor for disinfectant concentration, spray arm rotation sensor, detergent dispensing monitor.	Same as Predicate Device
Process Parameters	Same as predicate device with the addition of an endoscope connection test as part of the leak test. Temperature of rinse water has been increased to 49.5°C (from 45°C). Flow rate in all channels has increased due to the use of larger peristaltic pump tubing.	Same as Predicate Device

Software / firmware controls	Software controlled	Same as Predicate Device
Cycle comparisons	Cleans endoscopes and achieves high-level disinfection in 5 minutes at a minimum of 50°C.	Same as Predicate Device
Channels	Six channels for cleaning endoscopes with up to six channels.	Same as Predicate Device
Accessories	CIDEX® OPA Concentrate high level disinfectant and an enzymatic detergent (CIDEZYME GI) for cleaning medical instruments	Same as Predicate Device

7. SUMMARY OF NONCLINICAL TESTS

The EVOTECH® ECR Endoscope Cleaner & Reprocessor is a washer/disinfector for use with an enzymatic detergent and the high-level disinfectant CIDEX® OPA Concentrate Solution at 50° with an exposure time of 5 min to achieve cleaning and high-level disinfection of flexible endoscopes.

The EVOTECH® ECR Endoscope Cleaner & Reprocessor was tested in K040883 using the standard array of tests defined in the FDA Guidance on Premarket Notification [510(k)] Submission for Automated Endoscope Washers, Washer / Disinfectors, and Disinfectors Intended for Use in Health Care Facilities, August, 1993.

For simulated use testing, the high level disinfectant indicated for use with the EVOTECH® ECR Endoscope Cleaner & Reprocessor was tested for efficacy in a simulated use environment. A 6 Log10 reduction of *Mycobacterium terrae* was achieved when flexible endoscopes, contaminated with *Mycobacterium terrae* and artificial soil and were exposed to CIDEX OPA Concentrate In Use solution without cleaning. The diluted CIDEX® OPA Concentrate at an MEC of 0.055% OPA concentration at 50°C is effective against *Mycobacterium terrae* in artificial soil.

For in use testing, endoscopes used in a clinical environment were reprocessed in the EVOTECH® ECR Endoscope Cleaner & Reprocessor without manual cleaning. Sterility testing demonstrated no growth.

For biocompatibility, an endoscope reprocessed in the EVOTECH® ECR Endoscope Cleaner & Reprocessor was evaluated for residue levels. The analysis indicates that the level of OPA residual remaining on an endoscope is not likely to cause toxic effects in humans.

For material compatibility, the EVOTECH® ECR Endoscope Cleaner & Reprocessor using CIDEX OPA Concentrate In-Use solution was evaluated for its effect on materials commonly used in medical devices. Multiple disinfection cycles over extended periods of time resulted in minimal effect on the test articles. The effects

seen were similar to those seen with the predicate device for the high level disinfectant - CIDEX OPA Solution K991487.

The EVOTECH® ECR Endoscope Cleaner & Reprocessor was further tested in K061889 to determine its ability to high level disinfect and clean endoscopes. Both simulated use and in-use studies were completed. In both instances, endoscopes were contaminated and then processed in the "wash only" cycle in the EVOTECH® ECR Endoscope Cleaner & Reprocessor. Residual soil was quantified for both protein and total organic carbon (TOC). In all instances the residuals were below the predefined limit of 8.5ug/cm^2.

Additionally, because the wash cycle is intended to eliminate the need for manual cleaning, studies were completed comparing the residual soil after manual cleaning according to the procedures of the Society for Gastroenterology Nurses and Associates (SGNA) and cleaning in the EVOTECH® ECR Endoscope Cleaner & Reprocessor. In a non-inferiority trial, the washing of endoscopes in the EVOTECH® ECR Endoscope Cleaner & Reprocessor was determined to be non-inferior to washing of endoscopes following the SGNA procedure.

Endoscopes used in clinical procedures were processed through the "wash only" cycle of the EVOTECH® ECR Endoscope Cleaner & Reprocessor and then extracted for residual organic material. Processing in the EVOTECH® ECR Endoscope Cleaner & Reprocessor reduced the residual protein and TOC in all channels and surfaces to less than the predefined acceptance criteria, indicating that the EVOTECH® ECR Endoscope Cleaner & Reprocessor can clean clinically used endoscopes.

High-level disinfection of cleaned endoscopes was achieved. Endoscopes were contaminated with *Mycobacterium terrae* imbedded in soil. Soil was inoculated in channels and on the surfaces of endoscopes so that each endoscopes contained ≥8.5ug/cm^2 protein with >10^7 cfu/mL *M. terrae*. Endoscopes were disinfected in the EVOTECH® ECR Endoscope Cleaner & Reprocessor without manual or automated washing. After processing the contaminated endoscopes through the disinfect cycle only in the EVOTECH® ECR Endoscope Cleaner & Reprocessor, there was a >10^6 reduction in *M. terrae*.

Further high level disinfection testing and quantitative tuberculocidal testing have been completed for this submission demonstrating effectiveness of the OPAC solution at 0.042% concentration in the presence of 5% fetal bovine serum organic soil load within 5 minutes at 50-52°C using CIDEX OPA-C solution.

8. OVERALL PERFORMANCE CONCLUSIONS

Data presented in this submission indicate that the EVOTECH® ECR Endoscope Cleaner & Reprocessor is substantially equivalent to the Predicate Device.