DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 20, 2016

Advanced Sterilization Products (ASP)
Nazanin Yacobi
Senior Regulatory Affairs Program Lead
33 Technology Drive
Irvine, California 92618

Re: K152189
Trade/Device Name: EVOTECH® ECR Endoscope Cleaner and Reprocessor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: July 7, 2016
Received: July 11, 2016

Dear Nazanin Yacobi:

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,

Michael J. Ryan -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152189

Device Name
EVOTECH® Endoscope Cleaner and Reprocessor

Indications for Use *(Describe)*

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

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 for K152189

I. SUBMITTER

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Summary Date
July 12, 2016

II. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Trade Name: EVOTECH® ECR Endoscope Cleaner and Reprocessor
Common/Usual Name: Endoscope Cleaner and Reprocessor
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Product Code FEB
Product Classification: Class II
510(k) Number: K152189

III. PREDICATE DEVICE

EVOTECH® ECR Endoscope Cleaner and Reprocessor (K140977)

IV. DESCRIPTION OF DEVICE

The EVOTECH® ECR Endoscope Cleaner and 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 and 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 and Reprocessor must go through manual bedside pre-cleaning according to SGNA and facility guidelines prior to being placed in the EVOTECH® ECR Endoscope Cleaner and Reprocessor. If automatic cleaning is not available, or desired for the device by the user, the endoscope must also be manually cleaned by the user according to the endoscope manufacturer's instructions prior to being placed in the EVOTECH® ECR Endoscope Cleaner and Reprocessor.

After the endoscopes are connected to the EVOTECH® ECR Endoscope Cleaner and 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 soil present on or in the device.

The disinfectant is then mixed with incoming water, which is monitored to ensure that the temperature of the solution that is sprayed onto the surface of the device, and pumped through the lumens of the device, is at sufficient time and temperature to achieve high level disinfection. 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. EVOTECH® ECR has Data Transfer Interface (DTI) capability which provide dynamic host configuration protocol (DHCP) for connecting the EVOTECH® ECR system to hospital networks.

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 and Reprocessor User Guide.
The network connectivity software revision part of this 510(k) premarket notification allows the Hospital IT Department to connect the EVOTECH® ECR Endoscope Cleaner and Reprocessor to a Hospital Local Area Network (LAN) for transfer of cycle parameters to a server and if desired, to an Instrument Tracking System.

V. INDENTED USE

The EVOTECH® ECR Endoscope Cleaner and 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.

The new device has the same intended use as the predicate device.

VI. INDICATION 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 ^{o}C) 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.)

The new device has the same indication for use as the predicate device.

VII. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The EVOTECH® ECR Endoscope Cleaner and Reprocessor that is this subject of this submission is the same model as the predicate device cleared in K140977. The fundamental technological characteristics of the predicate devices are same as the device that is the subject of this 510(k). Design, materials, and functions of the Endoscope Cleaner and Reprocessor have not changed.

Table below contains a summary of the technological characteristics of the new device compared to the predicate device.

Feature	**Predicate Device:** K140977 **EVOTECH® ECR Endoscope Cleaner and Reprocessor**	**New Device:** K152189 **EVOTECH® ECR Endoscope Cleaner and Reprocessor**
System Design	Automated, stand-alone system with two operating reprocessing basin comprising hardware, software, and consumables, designed to perform cleaning and high level disinfection of flexible endoscopes. The system can reprocess two endoscopes at a time.	Same as predicate device

Disinfectant Used	CIDEX® OPA Concentrate Solution (Single Use)	Same as predicate device
System Performance	The system can perform block test, leak and endoscope connection test, washing (cleaning) and disinfection of flexible endoscopes. The system has a self-disinfect cycle. The cycle steps for each basin are monitored and separately controlled by the system software.	Same as predicate device
Endoscope and the Endoscope Cleaner and Reprocessor Materials and composition in contact with fluid pathways	powder coated aluminum glass, stainless steel, polyethylene, Neoprene, polypropylene, polyamide, Ultem, polycarbonate, polypropylene	Same as predicate device
System compatibility with associated chemical consumable	System material is compatible with CIDEX® OPA Concentrate high level disinfectant and an enzymatic detergent (CIDEZYME GI) for cleaning medical instruments	Same as predicate device
Network Connectivity	Static IP network connectivity.	Dynamic host configuration protocol (DHCP) network capability.

VIII. PERFORMANCE DATA

The modified device has the same intended use, indications for use, materials, design features and fundamental technological characteristics as the predicate device. The following performance data were provided in support of the substantial equivalence determination:

Software Verification and Validation Testing

Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern since prior to mitigation of hazards a

failure of the software could result in Minor Injury, either to a patient or to a user of the device.

Electrical Safety and Electromagnetic Compatibility (EMC)

The modified device has been tested for Radiated and Conducted Emissions according to the Standards EN 60601-1-2:2007 Class A and IEC 60601-1-2:2014 Class A, method CISPR 11:2009 (Amended by A1: 2010) Class A. All test results met the requirements of the Standards.

The modified device has been evaluated for safety in accordance with CAN/CSA-C22.2 No.: 61010-1 2004, UL 61010-1/R: 2008-10 and EN 61010-1:2001. The system meets the standards' requirements.

Other Testing

The EVOTECH® ECR Endoscope Cleaner and 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 and 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 and Reprocessor was tested for efficacy in a simulated use environment. A 6 Log_{10} 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 and Reprocessor without manual cleaning. Sterility testing demonstrated no growth.

For biocompatibility, an endoscope reprocessed in the EVOTECH® ECR Endoscope Cleaner and Reprocessor was evaluated for residue levels. The analysis indicates that the

level of OPA residual remaining on an endoscope following the rinse phase is not likely to cause toxic effects in humans.

For material compatibility, the EVOTECH® ECR Endoscope Cleaner and 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 and 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 and 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/cm2.

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 and Reprocessor. In a non-inferiority trial, the washing of endoscopes in the EVOTECH® ECR Endoscope Cleaner and 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 and Reprocessor and then extracted for residual organic material. Processing in the EVOTECH® ECR Endoscope Cleaner and 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 and 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 $\geq$8.5ug/cm^2 protein with >10^7 cfu/mL *M. terrae*. Endoscopes were disinfected in the EVOTECH® ECR Endoscope Cleaner and Reprocessor without manual or automated washing. After processing the contaminated endoscopes through the disinfect cycle only

in the EVOTECH® ECR Endoscope Cleaner and Reprocessor, there was a $>10^6$ reduction in *M. terrae*.

Further high level disinfection testing and quantitative tuberculocidal testing were completed for K140977 demonstrating effectiveness of the OPA Concentrate 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 Concentrate solution.

Additional cleaning and disinfection studies utilizing duodenoscopes with open and closed elevator wire channels were conducted.

Cleaning: Olympus, Pentax and Fujinon duodenoscopes (preconditioned by repeated articulation of the wire mechanisms with the distal tip immersed in artificial test soil and inoculated at the distal tip with a biopsy forceps in place), were cleaned using the EVOTECH® ECR System wash-only cycle. Residual protein and hemoglobin were extracted from the distal tip of all tested endoscopes and results showed that all test samples met the acceptance criteria of < 6.4 $\mu g/cm^2$ residual protein and "no residue" for Hemoglobin.

Due to the complexity of the manual cleaning instructions for duodenoscopes, it is recommended that endoscopes with open/closed elevator wire channels be manually cleaned as per manufacturer's instructions in addition to using the cleaning cycle of the EVOTECH® System.

High level disinfection: Worst case simulated use tests demonstrated that EVOTECH® ECR Endoscope Cleaner and Reprocessor achieved cleaning and high level disinfection of duodenoscopes with closed and open elevator wire channels. Olympus, Pentax and Fujinon duodenoscopes with closed and open elevator wire channels were contaminated with *Mycobacterium terrae* and reprocessed using the "disinfect only" cycle in the EVOTECH® ECR without cleaning. A 6 $\log_{10}$ reduction of *M. terrae* was achieved for all tested duodenoscopes.

IX. CONCLUSIONS

There is no change to the proposed device intended use/indication for use or fundamental scientific technology compared to the predicate device. The software verification and validation performed demonstrated that the software changes in the proposed device could not have a significant effect on the safety or effectiveness of the system. Therefore data presented in this submission indicate that the EVOTECH® ECR Endoscope Cleaner and Reprocessor is substantially equivalent to the Predicate Device, EVOTECH® ECR Endoscope Cleaner and Reprocessor (K140977).