July 15, 2019

Advanced Sterilization Products (ASP)
Laurie Cartwright
Director
33 Technology Drive
Irvine, California 92618

Re: K181472
Trade/Device Name: AEROFLEX(TM) Automatic Endoscope Reprocessor with AUTOSURE(TM) MRC Monitor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB, MED, JOJ
Dated: March 26, 2019
Received: March 27, 2019

Dear Laurie Cartwright:

This letter corrects our substantially equivalent letter of April 23, 2019.

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,

Clarence W. Murray Iii III -S

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181472

Device Name
AEROFLEX(TM) Automatic Endoscope Reprocessor (AER) with AUTOSURE(TM) MRC Monitor

Indications for Use *(Describe)*
The ASP AEROFLEX™ Automatic Endoscope Reprocessor (AER) with AUTOSURE™ MRC Monitor is indicated for use with high-level disinfectant ASP AERO OPA™ ortho-Phthalaldehyde Solution to achieve high-level disinfection of flexible semi-critical endoscopes. Manual cleaning of endoscopes is required prior to placement in the AER.

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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K181472 510(k) Summary

Advanced Sterilization Products
AEROFLEX™ Automatic Endoscope Reprocessor
with AUTOSURE™ MRC Monitor

General Information

Submitter Name:	Advanced Sterilization Products Division of Ethicon, Inc., a Johnson & Johnson company
Address:	33 Technology Drive Irvine, CA 92618
Contact Person:	Laurie Cartwright Director, Worldwide Regulatory Affairs Phone: 949-789-3877 Email: lcartwr@its.jnj.com Or Jamie Byun Manager, Regulatory Affairs Phone: 949-788-2067 Email: jbyun@its.jnj.com

Date Prepared:	20 April 2019

Device Name

Proprietary Name:	AEROFLEX™ Automatic Endoscope Reprocessor (AER) with AUTOSURE™ MRC Monitor
Common Name:	Endoscope washer/disinfector
Classification Name:	Accessories, Cleaning, For Endoscope
Device Class:	II
Product Code:	FEB
CFR Section:	21 CFR 876.1500

Predicate Device

The predicate device for the AEROFLEX Automatic Endoscope Reprocessor is the Olympus OER-Pro cleared under 510(k) K103264 (February 23, 2011). The predicate device for the AEROFLEX AER AUTOSURE MRC Monitor is the Browne CIDEX® OPA Test Strips cleared under 510(k) K991709 (October 8, 1999) and K081427 (June 11, 2008).

K181472 510(k) Summary

Device Description

The AEROFLEX Automatic Endoscope Reprocessor (AER) with AUTOSURE MRC Monitor is designed to provide high-level disinfection for flexible, submersible endoscopes that have been manually cleaned. The AEROFLEX system consists of the software-driven AER, the AUTOSURE MRC reagent, AERO-OPA™ disinfectant solution, and AEROZYME™ enzymatic detergent.

The AEROFLEX AER with AUTOSURE MRC Monitor is indicated for use with high-level disinfectant ASP AERO‑OPA ortho-Phthalaldehyde Solution to achieve high-level disinfection of semi-critical endoscopes; high-level disinfection requires that the AER be used with the AERO‑OPA Solution per its Instructions for Use.

Manual cleaning of endoscopes is required prior to placement in the AEROFLEX AER. After an endoscope is manually cleaned according to its manufacturer's recommended procedures, it is loaded into the AER. After starting the reprocessing cycle, the AER displays its progress during the cycle and signals that the cycle is complete on the control panel and with an audible tone.

The minimum recommended concentration (MRC) of ASP AERO‑OPA ortho‑Phthalaldehyde Solution is automatically checked and verified by the AER for every cycle using an integrated MRC monitor and reagent. The MRC monitor- tests the OPA concentration in every high-level disinfection cycle without the use of test strips; if the OPA concentration is below the MRC the system cancels the cycle and notifies the user.

To reduce user error and facilitate assurance of disinfection efficacy, the AEROFLEX System uses Radio Frequency Identification (RFID) technology to identify the ASP-branded consumables that are used with the system. Additionally, to enable electronic record-keeping by hospitals, the AEROFLEX system can be configured by users to transmit cycle printout information and/or print cycle records from the facility's network; the AEROFLEX System will also be compatible with ASP ACCESS™ Technology to allow automated record keeping.

Intended Use/Indications for Use

The ASP AEROFLEX Automatic Endoscope Reprocessor (AER) with AUTOSURE MRC Monitor is indicated for use with high-level disinfectant AERO-OPA ortho-phthalaldehyde Solution to achieve high-level disinfection of flexible semi-critical endoscopes. Manual cleaning of endoscopes is required prior to placement in the AER.

K181472 510(k) Summary

Technological Characteristics

The subject and predicate devices have similar characteristics based on their intended use in high level disinfection of flexible endoscopes. Both the AEROFLEX AER with AUTOSURE MRC Monitor and its predicate device are automatic endoscope reprocessors intended for high-level disinfection of flexible endoscopes; this is accomplished by putting the flexible endoscopes in contact with the disinfectant for the appropriate combination of time and temperature. Refer to the following tables for comparisons of predicate and proposed device characteristics.

AER Comparison Table

Device Characteristics	Predicate Device Olympus OER-Pro (K103264)	Subject Device AEROFLEX AER
Intended Use	High-level disinfection of Olympus flexible endoscopes and its accessories.	High-level disinfection for flexible, submersible endoscopes.
Indications for Use	The OER-Pro is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes and their accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Pro and Olympus flexible endoscopes and their accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Pro components and the endoscopes being reprocessed. Endoscopes must be subject to cleaning by the user prior to reprocessing; however, use of the OER-Pro enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Pro.	The ASP AEROFLEX Automatic Endoscope Reprocessor (AER) with AUTOSURE MRC Monitor is indicated for use with high-level disinfectant ASP AERO OPA ortho-Phthalaldehyde Solution to achieve high-level disinfection of flexible semi-critical endoscopes. Manual cleaning of endoscopes is required prior to placement in the AER.
Operational Principles	Inputs of water, proprietary detergent, and proprietary disinfectant. Contact for appropriate time and temperature controlled by software	Same
Basin	Single Basin	Same
Number of Scopes	Maximum two (one with certain models)	One
Disinfectant Used	Glutaraldehyde/Peracetic Acid	OPA
Disinfectant Use	Reuse	Same
Disinfectant Concentration Monitor	Test strips (visually read color change) provided by disinfectant manufacturer to test for minimum effective concentration (MEC)	Built-in minimum recommended concentration (MRC) monitor (colorimetric reading) to ensure that the disinfectant concentration is above minimum effective concentration (MEC)
Embedded RFID	Yes (for endoscope identification)	Yes (for disinfectant, detergent identification)
Operational Ambient Temperature	10-40 °C	15-30 °C

K181472 510(k) Summary

Device Characteristics	Predicate Device Olympus OER-Pro (K103264)	Subject Device AEROFLEX AER
Operational Relative Humidity	30-85%	10% to 85%
Operational Water temperature	Maximum 28 °C	5 °C to 35°C
Cycle Stages	Include wash, disinfection, rinse, air purge, and alcohol flush (Note: irrespective of nomenclature or order within the cycle)	Same
Fluid Heating	Present	Same
Cleaning method	Using EndoQuick® detergent. Exterior surfaces: Ultrasonic cleaning, turbulent bath Channel interiors: Fluid flushing	Using AEROZYME® detergent. Exterior surfaces: Turbulent bath, spray. Channel interiors: Fluid flushing
Cleaning time setting	3 – 10 minutes (Setting variable in 1 minute increments)	Not Applicable
Disinfection method	Exterior surfaces: Disinfectant solution immersion Channel interiors: Disinfectant solution flushing and filling Accessories: Disinfectant solution immersion	Same
Disinfection time setting	Acecide-C®: 7 minutes ALDAHOL® 1.8: 10 minutes	AERO-OPA®: Standard endoscopes: 8:05 minutes Duodenoscopes: 16:35 minutes
Disinfectant solution temperature setting	20 °C	32 °C – 36 °C
Alcohol flushing	Automatic flushing/draining	Same
Leak test	Visual-Bubble detection during immersion	Same
Power supply	Voltage: 120 Volts AC Frequency: 60Hz Input current: 5.5A Voltage fluctuation: +/-10%	Voltage: 120-240 Volts AC Frequency: 60Hz Input current: 12A Voltage fluctuation: +/-10%
Dimensions	450(W) x 977(H) x 765(D) mm	538(W) x 990(H) x 783(D) mm
Weight	120 kg (Dry)	74kg (Dry), 102kg (Operational)
Electrical Safety	UL/IEC 61010-1, 61010-2-040	Same
EMC Compliance	FCC Part 15, Subpart B, Class A	IEC 60601-1-2 and CISPR 11, Class A

K181472 510(k) Summary

MRC Monitor Comparison Table

Device Characteristics	Predicate Device Browne CIDEX OPA Test Strips (K991709 & K081427)	Subject Device AUTOSURE MRC Monitor
Intended Use	Concentration monitor for use in ortho-phthalaldehyde containing germicide solutions with a minimum effective concentration of 0.3%	Same
Functionality	Monitors active OPA concentration of CIDEX OPA Solution	Same
Design	Polypropylene strip with an indicator on one end. Manual concentration monitoring read by eye; color change indicates whether the OPA is above the minimum effective concentration (MEC).	Built-in to AEROFLEX AER. Automated colorimetric reading that ensures that the disinfectant is above the minimum effective concentration (MEC). If the MRC Monitor detects that the OPA is not at the appropriate concentration level, the user is notified via the AEROFLEX AER GUI and printer, the cycle is cancelled, and the user is advised to replace the OPA solution before the cycle is restarted.
Color Change	Test Strip color change is based on interaction of the test strip with aldehyde moiety of OPA which triggers a pH change reflected by color change based on OPA concentration.	Automated MRC assessment is based on OPA reaction with the MRC reagent which triggers a pH change. The pH is measured by the MRC monitor using visible light absorbance of a pH indicator in the reagent.
Test result interpretation	Processed test strip compared to color chart to determine if MRC check passed or not.	Automated process to determine if MRC check passed or not by indicating results on GUI screen
Shelf life	10 months	2 years
Sensitive to moisture	Yes	No
Reaction (OPA reaction forms base and causes PH change)	OPA reacts with sulfite	Same
Reaction (Acid neutralizes base formed by OPA reaction)	Acid is dosed in test strip	Acid is dosed in MRC reagent
Packaging	Test strips contained in polypropylene container with a flip top.	MRC Monitor built in to AEROFLEX AER. MRC Reagent contained in HDPE container with screw top lid.
Reaction (Color change with PH indicator)	pH indicator is included in test strip paper	pH indicator is included in MRC reagent
Contact/Mixing Time	1 second dip	60 second mixing
Reaction time	60 second read	30 second read
Pass/Fail check based on Color change	Compare to color chart visually	Absorbance measurement and recording done by machine automatically

K181472 510(k) Summary

As shown in the comparison tables, the overall differences between the AEROFLEX AER and its predicate device demonstrate that the devices have the same intended use and achieve the same goal of high-level disinfection of flexible endoscopes and ensuring that in-use OPA solution concentration meets minimum recommended concentration requirements. Although technological differences exist between the MRC monitor and its predicate, these differences have been successfully assessed through performance testing. The formulation of AERO-OPA, including ingredient amount and purpose, is identical to that of the currently marketed CIDEX® OPA solution.

Non-Clinical Data

Performance testing was conducted to satisfy the requirements for the AEROFLEX Automatic Endoscope Reprocessor that is the subject of this submission, as outlined in the Guidance for Industry and FDA Staff: *Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities* (August 1993). All testing yielded passing results. This testing is summarized in the following Table.

Summary of Performance Testing

Performance Testing	Description	Pass/ Fail
Process Parameter Physical Testing	To demonstrate the ability of the AEROFLEX AER system to achieve and maintain process parameters, standard and duodenoscope cycles were run with and without a scope (standard only). For each cycle type, sensor data recorded time, temperature, OPA concentration, channel flow, detergent delivery, and alcohol delivery. This information was compiled and summarized; all cycle parameters were within specification and tolerance and met acceptance criteria.	Pass
Simulated Use Testing	Study demonstrated the high-level disinfection capabilities of the AEROFLEX AER under worst-case conditions as recommended in FDA Guidance *Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities* (August 1993).	Pass
In-Use Testing	Study demonstrated the high-level disinfection capabilities of the AEROFLEX AER per FDA *Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities* (August 1993).	Pass
Self-Disinfection Efficacy	Study demonstrated the efficacy of the AEROFLEX AER self-disinfection processes.	Pass
Summative Usability Testing	Testing was conducted with representative end-user technicians and nurses, with user profiles typical of health care professionals involved in reprocessing flexible endoscopes for re-use.	Pass
System Verification Testing	Testing demonstrated that the system is functional and performs as intended.	Pass
MRC Monitor Testing	Testing demonstrated that the MRC Monitor successfully reads and reports AERO-OPA concentration.	Pass

K181472 510(k) Summary

Performance Testing	Description	Pass/ Fail
AUTOSURE MRC Reagent Verification	Testing demonstrated that the MRC reagent accurately detects the minimum recommended concentration (MRC) of OPA solution under various OPA solution and MRC reagent conditions.	Pass
AEROFLEX Cleaning Chemical Compatibility	Testing verified that common cleaning chemicals, such as bleach, alcohol, and common germicides or detergents do not affect the surfaces of the AEROFLEX AER.	Pass
AEROFLEX Chemical Compatibility with PMMA	Testing verified the compatibility of a PMMA component with liquids utilized in the AEROFLEX AER.	Pass
Basin and Lid Subsystem Verification	Testing verified that this subsystem fulfils its design requirements and performs as intended.	Pass
Consumables Management	Testing verified the ability of the consumables management subsystem to use RFID technology to ensure that only ASP AERO-OPA and AEROZYME XTRA consumables are used with the AEROFLEX AER.	Pass
Biocompatibility, Residuals and Rinsing Validation	Testing demonstrated that any residues associated with OPA, including any inert ingredients, by-products of chemical device reactions, derivatives of the treated devices, or other chemical residues that may be deposited/absorbed onto an endoscope under worst-case conditions, including 0.6% OPA and longest exposure time for a non-duodenoscope and duodenoscope during disinfection using the AEROFLEX AER, are nontoxic.	Pass
Stability and Reuse of OPA Solution	Testing demonstrated that the AERO-OPA Solution at onboard maintenance temperature, combined with worst case simulated use conditions for dilution and bioburden (introduced with endoscope reprocessing), can be used for up to 14 days or until the on-board MRC monitor cancels the cycle.	Pass
Bacterial Water Filter Validation	Testing demonstrated that the integrity of the bacterial water filter continues to meet acceptance criteria after 275 cycles. A recommended use life of 220 cycles has been established to provide a safety margin for replacement.	Pass
Flow Characteristic Evaluation	Numerous volume changes during purge-and-fill steps in the disinfection stage ensure that fresh disinfectant is consistently delivered to all areas of the endoscope channels well beyond time and temperature nominally required for achieving high-level disinfection. This margin of safety was demonstrated in simulated use testing that showed greater than 6-$\log_{10}$ reduction even under worst-case conditions.	Pass

Electrical Safety testing was conducted to verify compliance to the standards listed below. The testing provides a standardized level of assurance that the system is electrically safe when operated and maintained in accordance with the User's Guide.

- IEC/EN 61010-1:2010; *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements*
- IEC/EN 61010-2-040:2015; *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors used to treat medical material.*

- UL 61010-1:2012; *UL Standard for Safety Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements*
- UL 61010-2-040:2016; *UL Standard for Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors used to treat medical material.*
- CAN/CSA-C22.2 No. 61010-1 (2012); *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements*
- CAN/CSA-22.2 No. 61010-2-040 (2016); *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors used to treat medical material*

Electromagnetic Compatibility testing was completed to verify electromagnetic compatibility (Radiated and Conducted Emissions) according to the standards listed below; test results met the requirements of these standards.

Test Description	Standards	Test Result
Radiated Emissions Class A	IEC 60601-1-2:2014 CISPR 11:2010	Pass
Conducted Emissions Class A	IEC 60601-1-2:2014 CISPR 11:2010	Pass

Software Verification and Validation Testing was conducted, and documentation was provided within the submission as recommended by *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. Unit, Integration, and System level testing were successfully completed.

Clinical Data

No clinical data was generated in support of this Premarket Notification.

Conclusion

Based on the intended use, indications for use, technological characteristics, and non-clinical performance data, the AEROFLEX AER with AUTOSURE MRC Monitor is as safe, as effective, and performs as well or better than the legally marketed predicate devices, the Olympus OER-Pro cleared under K103264 and the Browne CIDEX OPA Test Strips cleared under K991709 and K081427.