DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19, 2017

Medivators Inc.
Megan Skaar
Regulatory Affairs Specialist
14605 28th Avenue North
Minneapolis, Minnesota 55447

Re: K172677
Trade/Device Name: Advantage Plus Pass Thru Automated Endoscope Reprocessing System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: November 20, 2017
Received: November 21, 2017

Dear Megan Skaar:

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" (21 CFR 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*
K172677

Device Name
Advantage Plus Pass Thru Endoscope Reprocessing System

Indications for Use *(Describe)*
Advantage Plus Pass-Thru Endoscope Reprocessing System tests, washes, disinfect and rinses endoscopes, such as fiberoptic and video endoscopes between patient uses. The Advantage Plus Pass-Thru system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes and related accessories. Manual cleaning of endoscopes is required prior to disinfection in the Advantage Plus Pass-Thru System.

The Advantage Plus Pass-Thru Endoscope Reprocessing System uses Rapicide PA High Level Disinfectant to provide high level disinfection of endoscopes when used according to the directions for use. The system uses Intercept Plus Detergent in its washing cycle at a concentration of 0.5%.

Rapicide PA Test Strips are used after the disinfection cycle to ensure that the used disinfectant is above the minimum recommended concentration (MRC) of 850 ppm peracetic acid; this ensures that the disinfectant was above MRC during the entire disinfection cycle. Rapicide PA should be used under the following contact conditions –
Contact Time: 5 minutes
Temperature: 30°C
MRC: 850ppm

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

510(k) Number:	K172677
Manufacturer:	Medivators Inc., a Cantel Medical Company
Address:	14605 28th Avenue North Minneapolis, MN 55447 (763) 553-3300
Official Contact:	Megan Skaar Regulatory Affairs Specialist, Medivators Inc.
Date:	19 December 2017
Trade Name:	Advantage Plus Pass Thru Endoscope Reprocessing System
Common Name:	Accessories, Cleaning, For Endoscope
Classification Name:	Endoscope and accessories
Product Code:	FEB
Device Class:	II
Regulation No:	Subject Device – Advantage Plus Pass Thru Endoscope Reprocessing System, 876.1500 Predicate Device Trade Name – Medivators Advantage Plus Endoscope Reprocessing System and Rapicide PA High Level Disinfectant (K082988 and K102996), 876.1500

1. Indications for Use

Advantage Plus Pass-Thru Endoscope Reprocessing System tests, washes, disinfects and rinses endoscopes, such as fiberoptic and video endoscopes, between patient uses. The Advantage Plus Pass-Thru system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes and related accessories. Manual cleaning of endoscopes is required prior to disinfection in the Advantage Plus Pass-Thru System.

The Advantage Plus Pass-Thru Endoscope Reprocessing System uses Rapicide PA High Level Disinfectant to provide high level disinfection of endoscopes when used according to the directions for use. The system uses Intercept Plus Detergent in its washing cycle at a concentration of 0.5%.

Rapicide PA Test Strips are used after the disinfection cycle to ensure that the disinfectant is above the minimum recommended concentration (MRC) of 850 ppm peracetic acid when used; this confirms that the disinfectant was above MRC during the entire disinfection cycle. Rapicide PA should be used under the following contact conditions –

Contact Time: 5 minutes
Temperature: 30°C
MRC: 850ppm

2. Device Description

The Advantage Plus Pass-Thru is an electro-mechanical Automatic Endoscope Reprocessor (AER) intended to high-level disinfect pre-cleaned endoscopes and their related accessories by exposing them to a peracetic acid based disinfectant – Rapicide PA disinfectant solution (cleared under 510k – K082988).

The subject device is closely related to its predicate the Advantage Plus Endoscope Reprocessing System cleared in 510k – K082988 and K102996 but differs in that it is designed in a "pass-thru" configuration. The subject device is intended to be built into a wall which separates 'clean' and 'dirty' sides. It provides the ability to load an endoscope from the dirty side and unload the disinfected endoscope from the clean side, thus preventing potential mix-up between high level disinfected and contaminated endoscopes.

Contaminated endoscopes are placed in the subject device from the 'dirty' side and appropriate connections to the endoscope channels are made. The system is designed to test for proper channel connectivity, channel blockages and leaks in the outer endoscope sheath. After the endoscope passes these tests, the system proceeds to the washing cycle with Intercept Plus detergent, and the high-level disinfection cycle. In the high-level disinfection cycle, Rapicide PA HLD is diluted by the incoming water to a minimum concentration of 850 ppm of peracetic acid. The system measures and maintains the temperature of this disinfectant solution to ensure that it is above the minimum recommended temperature of 30°C for Rapicide PA for effective High Level Disinfection to occur. Following the 5 minute disinfectant contact time, the user takes a sample to test for MRC (850 ppm of peracetic acid). Once the MRC test passes, the disinfectant is emptied from basin and drained out of the AER. The endoscope is then rinsed, dried and removed from the 'clean side' of the AER.

3. Comparison and Summary of Technological Characteristics for the Subject and Predicate Devices

The subject device – Advantage Plus Pass-Thru Endoscope Reprocessing System and its predicate device – Advantage Plus Endoscope Reprocessing System are very closely related and have the same intended use and fundamental technology.

Similarities Between Subject and Predicate Device

The Advantage Plus Pass-Thru and its predicate device have the same scientific technology including principle of operation, features and materials. Both devices have the same high level disinfection cycle. They use the same disinfectant chemistry – Rapicide PA under the same use conditions (30°C for 5 minutes at MRC of 850 ppm PAA) to high level disinfect endoscopes. They have identical chemistry dosing mechanisms to produce equivalent concentration of disinfection solution. Additionally, both

the devices have the same fluid flow rate and pathway. The Advantage Plus Pass-Thru System is constructed of the same materials, metals and polymers, as its predicate device.

Differences Between Subject and Predicate Device

The subject device provides the ability to load an endoscope into the AER from the dirty, contaminated side and unload the disinfected scope from the clean side – creating the pass-thru system. To facilitate this system configuration, the basin door arrangement was altered from the arrangement of the predicate device. There were no changes in critical parameters to achieve high level disinfection with the alteration of a pass-thru door configuration. **Verification and validation of software and performance testing on the subject device pass-thru configuration demonstrates the configuration difference between the subject device and the predicate device does not impact the safety and effectiveness profile of the devices.** The pass-thru configuration of the subject AER physically separates the 'clean' and 'dirty' sides of the reprocessing unit and hence reduces the risk of cross contamination as demonstrated in the performance testing outlined in Table 2 below.

Performance bench testing, included in Section 4 of this summary, supports substantial equivalence of the pass-thru system configuration. A device comparison table which supports substantial equivalence of the subject device to the predicate device is provided below –

Table 1 – Predicate Comparison Table

Important Parameters	Subject Device – Advantage Plus Pass-Thru	Predicate Device – Advantage Plus (cleared under 510k - K082988 and K102996)
Intended Use	Advantage Plus Pass-Thru Endoscope Reprocessing System tests, washes, disinfects and rinses endoscopes, such as fiberoptic and video endoscopes, between patient uses. The Advantage Plus Pass-Thru system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes and related accessories. Manual cleaning of endoscopes is required prior to disinfection in the Advantage Plus Pass-Thru System. The Advantage Plus Pass-Thru Endoscope Reprocessing System uses Rapicide PA High Level Disinfectant to provide high level	Medivators Advantage Plus Endoscope Reprocessing System tests, washes, disinfects and rinses endoscopes, such as fiberoptic and video endoscopes, between patient uses. The Advantage Plus system is indicated to provide high level disinfection of heat sensitive semi-critical endoscopes and related accessories. Manual cleaning of endoscopes is not required prior to disinfection in the Advantage Plus Pass-Thru System. The Advantage Plus Endoscope Reprocessing System uses Rapicide PA High Level Disinfectant to provide high level disinfection of

	disinfection of endoscopes when used according to the directions for use.	endoscopes when used according to the directions for use.
Product Code	FEB	FEB
FDA Regulation	21 CFR§ 876.1500	21 CFR§ 876.1500
Pass-Thru Configuration/ AER separates Clean and Dirty Side?	Yes	No
Type of Machine Function	Electro-mechanical	Electro-mechanical
System Technology Features	The system performs endoscope connection test, leak and channel blockage test, washing (cleaning), disinfection and rinsing. The cycle steps for each basin are monitored. Built in safety features and alarms.	The system performs endoscope connection test, leak and channel blockage test, washing (cleaning), disinfection and rinsing. The cycle steps for each basin are monitored. Built in safety features and alarms.
Disinfection time, temperature and minimum recommended concentration	Rapicide PA – 5 minutes at 30°C; 850ppm Peracetic acid MRC	Rapicide PA – 5 minutes at 30°C; 850ppm Peracetic acid MRC
Detergent used in cleaning cycle	Intercept Plus Detergent	Intercept Detergent
Disinfection efficacy	$>10^6$ log reduction of *Mycobacterium terrae*	$>10^6$ log reduction of *Mycobacterium terrae*
Manual cleaning required before use?	Yes	Yes (per K082988) however if the automated cleaning cycle is used, manual cleaning is not required (per K102988)
Performs leak test?	Yes	Yes
Performs channel connection and blockage test?	Yes	Yes
Post-disinfection treatment	Optional alcohol purge followed by air purge of endoscope channels	Optional alcohol purge followed by air purge of endoscope channels

4. Summary of Non-Clinical Performance Data

Medivators has conducted the following testing to demonstrate the substantial equivalence of Advantage Plus Pass Thru AER –

- Performance Testing – Identical performance testing has been conducted on the subject and predicate devices to ensure the Advantage Plus Pass-Thru meets equivalent acceptance criteria as the Advantage Plus. This testing confirms the subject device performs with the same safety

and effectiveness as the predicate device, please refer to the table below for a brief discussion of the performance testing.

Table 2 – Comparison of Non-Clinical Performance Tests for the Predicate and Subject Devices

Performance Testing	Acceptance Criteria	Results
Simulated-Use Testing – Demonstrates that when used as indicated, the system high level disinfects endoscopes using Rapicide PA HLD and Intercept Plus detergent.	Achieve 6-log reduction of the test organism in each endoscope channel and endoscope exterior.	Pass
Clinical In-Use Testing – Demonstrates that when used as indicated, the system high level disinfects nominal endoscopes using Rapicide PA HLD after patient/clinical use.	Demonstrate no viable organisms remain after reprocessing.	Pass
Water-Line/Self-Disinfection Cycle Testing – Evaluation of the bactericidal effectiveness of the self-disinfection cycle (SDC) and additional subject device biofilm analysis by quantitative Polymerase Chain Reaction gene expression.	Survivors after the SDC must be ≤ 10 CFU of test organism per 100 mL. Absence of biofilm formation following self-disinfection cycle.	Pass
Rinse Residual Testing – Evaluation of residual levels of Rapicide PA and Intercept Plus to demonstrate that endoscopes reprocessed in the AER are safe for both patients and users.	Any chemistry residuals must be equal to or lower than the lowest reports LD_{50} exposure with a 10-fold safety margin.	Pass
Material Compatibility – Demonstrates the system compatibility with Rapicide PA High Level Disinfectant and subject device compatibility with Intercept Plus Detergent.	Acceptance criteria included dimensional and weight changes <5%, visual observations and FTIR spectra.	Pass
Critical Parameter/Component Functionality Testing – Demonstrates the system consistently and reliably delivers the specified physical process parameters.	All critical process parameters must achieve and maintain required specifications.	Pass

- Electrical Safety and Electromagnetic Compatibility – Electrical safety and electromagnetic compatibility testing has been conducted to demonstrate compliance with IEC 61010 and IEC 61326.

- Software Validation – Software validation testing has been conducted to demonstrate compliance with IEC 62304.
- Human Factors/Usability Evaluation – Human factors testing has been conducted to demonstrate compliance with ISO 62366.

5. Conclusion

The Advantage Plus Pass-Thru intended use and fundamental scientific technology is the same as the predicate device, the Advantage Plus AER. Performance testing, software verification and validation testing and human factors validation demonstrate that the subject device pass-thru configuration is substantial equivalent to the predicate device. Therefore, based on the intended use, technology and performance data, the subject device is as safe and as effective as the legally marketed predicate device. The Advantage Plus Pass-Thru AER is substantially equivalent to predicate device Advantage Plus AER cleared in 510(k)s – K082988 and K102996.