DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 21, 2016

Medivators Inc.
Kristin Padilla
Regulatory Affairs Associate
14605 28th Ave. North
Minneapolis, Minnesota 55447

Re: K162128
Trade/Device Name: Scope Buddy Plus Endoscope Flushing Aid
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: November 23, 2016
Received: November 28, 2016

Dear Kristin Padilla:

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,

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)*
K162128

Device Name
Scope Buddy Plus Endoscope Flushing Aid

Indications for Use *(Describe)*
Scope Buddy Plus Endoscope Flushing Aid is an electro-mechanical device intended to pump fluids through channels of flexible, immersible endoscopes during the endoscope manual cleaning process.

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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MEDIVATORS
A Cantel Medical Company

510(k) Summary K162128

Date Prepared:	December 12, 2016
Manufacturer:	Medivators Inc., a Cantel Medical Company
Address:	14605 28th Avenue North Minneapolis, MN 55447 (800) 328-3345
Official Contact:	Kristin Bergeson Padilla Regulatory Affairs Associate, Medivators Inc.
Trade Name:	**Scope Buddy Plus Endoscope Flushing Aid**
Common Name:	Accessories, Cleaning, For Endoscope
Classification Name:	Endoscope and accessories
Product Code:	FEB
Device Class:	II
Regulation No:	876.1500

Medivators Inc. has supplied the following information to the US Food and Drug Administration to support substantial equivalence of Scope Buddy Plus to other endoscope flushing aid devices currently cleared for sale in the United States of America.

1. **Intended Use**
   Scope Buddy Plus Endoscope Flushing Aid is an electro-mechanical device intended to pump fluids through channels of flexible, immersible endoscopes during the endoscope manual cleaning process.

2. **Device Description**
   The subject device is intended to provide fluid delivery to endoscope channels in the same manner as a manual syringe would be used during the manual cleaning phase of endoscope reprocessing as defined by the endoscope manufacturer's instructions. The subject device utilizes an external peristaltic pump and 24-hour multi-use connection tubing (tubing used for 24 hours with multiple endoscopes and then discarded) to deliver specific volumes of detergent solution and rinse water to the endoscope channels during the manual cleaning phase. These fluid volumes are defined by the endoscope manufacturer. Scope Buddy Plus is intended to be used only during the manual cleaning phase of endoscope reprocessing, in conjunction with the instructions and labeling provided by the endoscope manufacturer, to deliver an endoscope manufacturer specified volume of fluid to the endoscope channels. The subject device is not an endoscope washer-disinfector and does not bear labeling claims for direct cleaning efficacy or high-level disinfection efficacy for endoscope reprocessing.

3. **Comparison to Other Devices in Commercial Distribution Within the United States**
   Scope Buddy Plus is equivalent in intended use, function and fundamental technology to its predicate device, Fluid Pump CP-3 cleared under 510(k) K914524.

Similarities Between Subject and Predicate Devices

Scope Buddy Plus and its predicate device, Fluid Pump CP-3, have the same intended use, fundamental technology and performance. Both the subject device and the predicate device are similar in that the intended use replicates the mechanical means of fluid delivery to endoscope channels in the same manner as a manual syringe would be used. Both devices are used during the manual cleaning phase of endoscope reprocessing to deliver fluid volumes to the endoscope channels according to the endoscope manufacturer's instructions. Both devices are similar in fundamental technology and general performance.

Differences Between Subject and Predicate Devices

The main notable differences between the subject device, Scope Buddy Plus, and the predicate, Fluid Pump CP-3, are the connection tubing and software. Scope Buddy Plus utilizes an external peristaltic pump with 24-hour multi-use connection tubing (tubing used for 24 hours with multiple endoscopes and then discarded) while the predicate device utilizes internal fluid pumps with reusable tubing set connections. The subject device utilizes a software controlled user interface while the predicate device utilizes analog circuitry control. In addition, the subject device does not bear labeling claims for direct cleaning efficacy or high-level disinfection efficacy for endoscope reprocessing while the predicate device bears cleaning and disinfection efficacy claims.

A device comparison table which supports substantial equivalence of the subject device to the predicate device is provided below:

Table 1 – Device Comparison Table

Device Parameters	Subject Device – Scope Buddy Plus Endoscope Flushing Aid	Predicate Device – Fluid Pump CP-3 (K914524)
Trade Name	Scope Buddy Plus Endoscope Flushing Aid	Fluid Pump CP-3
Regulation Number	876.1500	876.1500
Device Class	Class II	Class II
Certification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Product Code	FEB	FEB
Intended Use	To pump fluids through the channels of flexible, immersible endoscopes	To pump fluids through the channels of flexible, immersible endoscopes
Type of Machine Function	Electro-mechanical	Electro-mechanical
Connection Tubing	24 hour multi-use connection tubing	Reusable tubing set connections
Software Controlled User Interface	Yes	No
Fluid Delivery Flow Rate Performance	Meet or exceed the endoscope manufacturer's requirements for fluid delivery through endoscope channels	Meet or exceed the endoscope manufacturer's requirements for fluid delivery through endoscope channels
Mechanism of Action	External peristaltic fluid pump with built-in timer	Internal fluid pump with built-in timer
Schematic Flow	Flushing liquids are placed into a	Flushing liquids are placed into a

	container, pre-cleaning basin or sink. A tubing set pulls fluid from the container, basin or sink via action from the external peristaltic pump. The fluid continues to flow through the tubing set which is connected to the endoscope channels. The fluid is then pumped through the endoscope channels.	medical washing tray. An intake tubing set pulls fluid from the washing tray and into and through two internal fluid pumps. The fluid is then expelled from the pumps through discharge tubing sets which are connected to the endoscope channels. The fluid is then pumped through the endoscope channels.
Amount of Cleaning Liquid	Amount sufficient to meet or exceed the endoscope manufacturer's requirements for volume of fluid delivery through endoscope channels.	Amount sufficient to meet or exceed the endoscope manufacturer's requirements for volume of fluid delivery through endoscope channels.
Time for Cleaning Liquid Circulation	Variable, the length of the cleaning liquid circulation time is sufficient to deliver cleaning liquid volumes that meet or exceed the endoscope manufacturer's requirements.	Variable, the length of the cleaning liquid circulation time is determined by setting a timer.

4. Summary of Non-Clinical Performance Data

Medivators has conducted the following testing to demonstrate the substantial equivalence of Scope Buddy Plus:

- Functional Performance Testing
  - Detergent Dosing to demonstrate the ability of the subject device to dose a set volume of detergent.
  - Fluid Delivery Flow Rate to determine the flushing times required by the subject device to meet endoscope manufacturers' requirements for fluid volumes delivered to endoscope channels during manual cleaning.
- Electrical Safety and Electromagnetic Compatibility in accordance with IEC 61010-1 and IEC 61326-1, respectively.
- Software Validation as recommended per FDA's guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Human Factors/Usability Evaluation to validate that users can safely and effectively use the subject device per IEC 62366-1 and FDA's guidance for Applying Human Factors and Usability Engineering to Medical Devices.

5. Conclusion

Scope Buddy Plus is substantially equivalent to predicate device Fluid Pump CP-3 cleared under 510(k) K914524. Based on the intended use, fundamental technology and performance data, the subject device Scope Buddy Plus is substantially equivalent to and is as safe and as effective as the legally marketed predicate device.