January 14, 2022

Medivators Inc
Mark Arnold
Principal Regulatory Affairs Specialist
14605 28th Ave North
Minneapolis, Minnesota 55447

Re: K213833
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: December 7, 2021
Received: December 9, 2021

Dear Mark Arnold:

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, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213833

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 the channels of flexible, immersible endoscopes during the manual cleaning process of endoscope reprocessing.

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
SCOPE BUDDY PLUS Endoscope Flushing Aid

Medivators Inc
14605 28th Avenue North
Minneapolis, MN 55447

Contact: Mark Arnold
Principal Regulatory Affairs Specialist
Tel: 844-348-5636
Fax: 844-348-5637

Summary Date: January 13, 2022

1. Device Name

Trade Name: **SCOPE BUDDY PLUS Endoscope Flushing Aid**

Device Class: II

Common/Generic Name: Circulating Pump

Classification Name: Accessories, Cleaning, For Endoscope

Classification Number: 21 CFR 276.1500

Product Code: FEB

2. Predicate Device

SCOPE BUDDY PLUS Endoscope Flushing Aid, cleared under K162128

3. Description of Device

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. The minimum fluid volumes are defined by the endoscope manufacturer. SCOPE BUDDY PLUS Endoscope Flushing Aid 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 a volume of fluid to the endoscope channels which exceeds the minimum fluid volumes specified by the endoscope manufacturer. 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.

4. Indications for Use

SCOPE BUDDY PLUS Endoscope Flushing Aid is an electro-mechanical device intended to pump fluids through the channels of flexible, immersible endoscopes during the manual cleaning process of endoscope reprocessing.

5. Summary of Technical Characteristics

A comparison of technical characteristics versus the predicate is summarized in **Table 5-1** below.

Feature	Subject Device – SCOPE BUDDY PLUS Endoscope Flushing Aid	Predicate Device – SCOPE BUDDY PLUS Endoscope Flushing Aid (K162128)	Comparison
Indications for Use	SCOPE BUDDY PLUS Endoscope Flushing Aid is an electro-mechanical device intended to pump fluids through the channels of flexible, immersible endoscopes during the manual cleaning process of endoscope reprocessing.	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.	Same
Type of Machine Function	Electro-mechanical	Electro-mechanical	Same
Connection Tubing	24-hour connection tubing	24-hour connection tubing	Same
Air Purge	Yes	Yes	Same
Cleans or Reprocesses the Exterior of Endoscopes	No	No	Same
Performs Leak Test	No	No	Same
Automatic Detergent Dosing	Yes	Yes	Same
Temperature Monitoring	Yes	Yes	Same
Software Controlled User Interface	Yes	Yes	Same
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	Same
Mechanism of Action	External peristaltic fluid pump with built-in timer	External peristaltic fluid pump with built-in timer	Same

Feature	Subject Device – SCOPE BUDDY PLUS Endoscope Flushing Aid	Predicate Device – SCOPE BUDDY PLUS Endoscope Flushing Aid (K162128)	Comparison
Schematic Flow	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.	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.	Same
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.	Same
Time for Cleaning Liquid Circulation	Variable. The length of the cleaning liquid circulation time is set by an adjustable timer, and the range 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 set by an adjustable timer, and the range is sufficient to deliver cleaning liquid volumes that meet or exceed the endoscope manufacturer's requirements.	Same

Table 5-1: Physical Description and Technological Properties vs the Predicate Device

6. Summary of Non-Clinical Performance Data

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-2** below.

Test	Acceptance Criteria	Conclusion
Fluid Delivery Flow Rate Verification	Meet manufacturers minimum requirements for individual channel flushing volumes.	PASS

Test	Acceptance Criteria	Conclusion
Tubing Durability Verification	The 24-hour tubing shall withstand at least 40 full automatic cycles without leaking.	PASS
Software Verification	Verification steps outlined in procedure must be met for acceptance of the protocol.	PASS

Table 5-2: Summary of Non-Clinical Performance Data

7. Conclusion

Based on the conclusions for the non-clinical performance data, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K162128), Class II (21 CFR 876.1500), product code FEB.