July 11, 2019

Partnership Medical Limited
Silbiano Gonzales
Consultant
QRC Consulting, LLC
10422 Huebner Road, Apt# 508
San Antonio, TX 78240

Re: K181418
Trade/Device Name: ScopeFlow Pure™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: June 6, 2019
Received: June 10, 2019

Dear Silbiano Gonzales:

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,

Shanil P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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)*
K181418

Device Name
ScopeFlow Pure™

Indications for Use *(Describe)*

The ScopeFlow Pure™ is designed to be used in conjunction with a flexible endoscope to insufflate air/CO2 and supply sterile water during endoscopic procedures. The ScopeFlow Pure™ is compatible with the different sterile water bottles available. It is intended to be used for 24 hours and then disposed of.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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I. SUBMITTER

Applicant Name: Partnership Medical Limited
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Fenton, Stoke on Trent, ST4 3PE
Contact Person: Rob Hartley, Director

US Contact / Correspondent: QRC Consulting, LLC.
Silbiano Gonzales, Consultant
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Phone: (210) 287-9558
Email: silbianog@sbcglobal.net

II. DEVICE

Trade Name: ScopeFlow Pure™
Catalog Number:

CATALOG (PART) NUMBERS				
SFP145	SFP145CO2	SFP145CO2S	SFP1451 HYBRID	SFP1452 HYBRID
SFP160	SFP160CO2	SFP160CO2S	SFP1601 HYBRID	SFP1602 HYBRID
SFP165	SFP165CO2	SFP165CO2S	SFP1651 HYBRID	SFP1652 HYBRID

Common or Usual Name: Endoscopic Irrigation/Suction System
Regulation Name: Endoscope and accessories
Regulation Number: 21 CFR 876.1500
Device Class: II
Product Code: OCX

The Gastroenterology/Urology devices panel has classified Endoscopic Irrigation/Suction System as Class II under 21 CFR §870.1500. OCX is the product code that has been assigned for these types of devices.

PART 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

Subpart B--Diagnostic Devices

Sec. 876.1500 Endoscope and accessories

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b) (2) are exempt from the premarket notification procedures in subpart E of part 807of this chapter, subject to the limitations in 876.9.

Product Code: OCX

Device: Endoscopic irrigation/suction system

Definition: To supply sterile water, other solutions and/or suction to endoscopes during endoscopic procedures.

III. DEVICE DESCRIPTION

The ScopeFlow Pure™ is available in fifteen (15) configurations:

CATALOG (PART) NUMBERS				
SFP145	SFP145CO2	SFP145CO2S	SFP1451 HYBRID	SFP1452 HYBRID
SFP160	SFP160CO2	SFP160CO2S	SFP1601 HYBRID	SFP1602 HYBRID
SFP165	SFP165CO2	SFP165CO2S	SFP1651 HYBRID	SFP165 HYBRID

The ScopeFlow Pure™ is used to convey sterile water from an external water source to a flexible endoscope to aid its function.

The ScopeFlow Pure™ consists of:

1) PVC tubing is used provide the method of transferring the sterile water from the external source to the flexible endoscope. This sterile water is used to clean the lens of the flexible endoscope during operation or to assist in improving the flexible endoscopes visual field.

2) An endoscope connector at the distal end of the device. For the ScopeFlow Pure™ the three different connectors are designed to fit Olympus, Pentax and Fujinon endoscopes. The connectors are manufactured from medical grade plastic, which is used as an outer housing and medical grade TPE or silicone which are used as seals to prevent water and air from escaping during use.

The ScopeFlow Pure™ functions by using a two parallel tubes configuration to supply air to the water bottle and provide water to the flexible endoscope.

The HYBRID configuration consists of the ScopeFlow Pure™ and an EndoStream™ units being used together. The HYBRID models function in the same way but instead of using a separate sterile bottle for irrigation of the lens and irrigation of the GI Tract, one bottle of sterile water is used as the feed for both, the Hybrid has only one screwcap.

The ScopeFlow Pure™ is available in fifteen (15) configurations, according to endoscope manufacturer:

PFE/PML Product Code	Endoscope type
SFP145	ScopeFlow Pure™ for Olympus 140 & 240 series endoscopes and higher
SFP145CO2	ScopeFlow Pure™ for Olympus 140 & 240 series endoscopes and higher with CO2
SFP145CO2S	ScopeFlow Pure™ for Olympus 140 & 240 series endoscopes and higher with CO2 (short)
SFP1451 HYBRID	ScopeFlow Pure™ for Olympus 140 & 240 series endoscopes and higher with CO2 and EndoStream™ PFE130
SFP1452 HYBRID	ScopeFlow Pure™ for Olympus 140 & 240 series endoscopes and higher with CO2 and EndoStream™ PFE230
SFP160	ScopeFlow Pure™ for Pentax endoscopes
SFP160CO2	ScopeFlow Pure™ for Pentax endoscopes with CO2
SFP160CO2S	ScopeFlow Pure™ for Pentax endoscopes with CO2 (short)
SFP1601 HYBRID	ScopeFlow Pure™ for Pentax endoscopes with CO2 (short) and EndoStream™ PFE130
SFP1602 HYBRID	ScopeFlow Pure™ for Pentax endoscopes with CO2 (short) and EndoStream™ PFE230

PFE/PML Product Code	Endoscope type
SFP165	ScopeFlow Pure™ for Fujinon endoscopes G5 and newer
SFP165CO2	ScopeFlow Pure™ for Fujinon endoscopes G5 and newer with CO2
SFP165CO2S	ScopeFlow Pure™ for Fujinon endoscopes G5 and newer with CO2 (short)
SFP1651 HYBRID	ScopeFlow Pure™ for Fujinon endoscopes with CO2 & EndoStream™ PFE230
SFP1652 HYBRID	ScopeFlow Pure™ for Fujinon endoscopes with CO2 & EndoStream™ PFE130

IV. INDICATIONS FOR USE

The ScopeFlow Pure™ is intended to be used in in conjunction with a flexible endoscope to insufflate air/CO_2 and supply sterile water during endoscopic procedures. The ScopeFlow Pure™ is compatible with the different sterile water bottles available. It is intended to be used for 24 hours and then disposed of.

V. PREDICATE DEVICES

The ScopeFlow Pure™ is designed to be used with commercially available endoscopes and intended to be used in conjunction with a flexible endoscope to insufflate air and supply sterile water during endoscopic procedures. The ScopeFlow Pure™ is compatible with different commercially available sterile water bottles.

The ScopeFlow Pure™ legally marketed predicates, to which Partnership Medical Limited is claiming equivalence are:

Predicate Device for the ScopeFlow Pure™		
Company	**Predicate Device Name**	**FDA 510(k) Number**
Medivators	EndoSmart Bottle, Rinse and Insufflation System [Model: 100145U / 100150U / 100160U / 100165CO2U / 100145CO2U / 100150CO2U / 100145CO2EXTU / 100150CO2EXTU / 100165CO2EXTU]	K140753
Endo SmartCap Company	The Endo SmartCap [Model: 100145 / 100150]	K971125

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The ScopeFlow Pure™ is substantially equivalent to both the Medivators (Endo Smart Bottle Rinse and Insufflation System, K140753) and the Endo SmartCap Company (Endo Smart Cap, K971125).

Characteristic Compared	**Our Device**	**Predicate 1**	**Predicate 2**
Manufacturer	Partnership Medical, Ltd	Endo SmartCap™ Company	Medivators, Inc.
Device	ScopeFlow Pure™	The Endo SmartCap™	Endo Smart Bottle, Rinse and Insufflation System
510(k) Number	-	K971125	K140753
Indication	The ScopeFlow Pure™ is intended to be used in conjunction with a flexible endoscope to insufflate air/CO_2 and supply sterile water during endoscopic procedures. The ScopeFlow Pure™ is compatible with the different sterile water bottles available. It is intended to be used for 24 hours and then disposed of.	ENDO SMARTCAP™ is intended to supply sterile water to series 10, 100 and 130 Olympus endoscopes when connected to a commercially available sterile water bottle.	EndoSmart Bottle is intended to be used with an air or CO2 source and/or a pump along with a sterile water source to supply air or CO2 and sterile water to an endoscope during endoscopic procedures.

Characteristic Compared	Our Device	Predicate 1	Predicate 2
Product Code/Class	OCX	OCX	OCX
Principle of Operation	used in conjunction with a flexible endoscope to insufflate air and supply sterile water during endoscopic procedures.	Similar	Similar
Difference	No difference	No difference	No difference
Materials of Construction	Per section 16	Identical	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

VII. PERFORMANCE DATA

Performance testing was completed (per respective standards) for sterilization validation (ISO 11135), package and shelf-life testing and biocompatibility.

The ScopeFlow Pure™ product was evaluated for cytotoxicity, intracutaneous irritation and sensitization per biocompatibility requirements according to ISO 10993.

The ScopeFlow Pure™ products were also tested to demonstrate functionality and performance integrity.

VIII. CONCLUSIONS

Partnership Medical Limited considers the ScopeFlow Pure™ to be substantially equivalent to the legally marketed predicate device listed above, and safe and effective for the intended use. The conclusion is based on similarities in indications for use, materials, performance testing, technological characteristics, principle of operation and design features. Any differences do not raise any new issues of safety or effectiveness.