July 11, 2019

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

Re: K181457
Trade/Device Name: EndoStream™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: June 3, 2019
Received: June 11, 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)*
K181457

Device Name
EndoStream™

Indications for Use *(Describe)*
The EndoStream™ tubing is intended to provide irrigation via sterile water supply during gastrointestinal (GI) endoscopic procedures when used in conjunction with an irrigation pump.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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I. SUBMITTER

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

US Contact / Correspondent: QRC Consulting, LLC.
Silbiano Gonzales, Consultant
Address: 5623 Hamilton Wolfe Rd.,
Apt. #921 San Antonio, TX
78240
Phone: (210) 287-9558
Email: silbianog@sbcglobal.net

II. DEVICE

Trade Name: EndoStream™
Catalog Number:

| CATALOGUE (PART) NUMBERS | | |
|---|---|---|
| **Catalogue number** | **Description** | **Compatibility** |
| PFE130 | EndoStream™ Irrigation Tubing | Olympus®, Pentax®, EndoStratus™, Scope Assist® |
| PFE230 | EndoStream™ Irrigation Tubing | EGP-100E®, Olympus®, ScopeAssist® and ERBE™ |

Common or Usual Name: Endoscopic Irrigation/Suction System
Regulation Number: 21 CFR 876.1500
Regulatory Name: Endoscope and accessories
Regulatory Class: 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.

Premarket Review: Office of Product Evaluation and Quality

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices

THT3A2: Gastroenterology and Endoscopy Devices Team

III. DEVICE DESCRIPTION

The EndoStream™ is available in two (2) configurations:

| CATALOGUE (PART) NUMBERS | | |
|---|---|---|
| **Catalogue number** | **Description** | **Compatibility** |
| PFE130 | EndoStream™ Irrigation Tubing | Olympus®, Pentax®, EndoStratus™, Scope Assist® |
| PFE230 | EndoStream™ Irrigation Tubing | EGP-100E®, Olympus®, ScopeAssist® and ERBE™ |

Partnership Medical Ltd introduced the EndoStream™ (product code PFE230) in 2014 which fits the EGP-100, Olympus and ERBE pumps and this product has been supplied to over 50 Hospitals in the UK since that time. The Scope Assist tubing version (product code PFE130) was introduced in 2016 to fit our own Scope Assist pump, but also fits the EndoStratus and Olympus OPF-2 pumps.

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

The EndoStream™ consists of the following:

1) PVC tubing is used to 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 is located at the distal end of the device. The EndoStream™ uses a medical grade plastic check valve, which connects to the flexible endoscope via an adaptor.

The EndoStream™ functions by using a single lumen in conjunction with a peristaltic pump to provide water to the flexible endoscope.

**EndoStream™** connects a sterile water supply into the proximal end of an endoscope. Once connected, EndoStream™ allows sterile water to flow into the endoscope which carries it into the Gastrointestinal (GI) tract to flush out the GI tract during endoscopic procedures. There are 2 configurations for use with different pumps.

| CATALOGUE (PART) NUMBERS | | |
|---|---|---|
| **Catalogue number** | **Description** | **Compatibility** |
| PFE130 | EndoStream™ Irrigation Tubing | Olympus®, Pentax®, EndoStratus™, Scope Assist® |
| PFE230 | EndoStream™ Irrigation Tubing | EGP-100E®, Olympus®, ScopeAssist® and ERBE™ |

The EndoStream™ tubing is designed to be used in conjunction with a peristaltic pump which attaches to a flexible endoscope to supply sterile water for irrigation during endoscopic procedures. The EndoStream™ tubing is compatible with all commercial sterile water bottles.

EndoStream™ is a tubing with a cap which directly screws onto a sterile water bottle. The tubing extremity connects to the endoscope via the pump head on a peristaltic irrigation pump.

A back flow valve is integrated in the extremity of each EndoStream™ tubing ensuring the unidirectional flow from the sterile water bottle to the endoscope, thus guaranteeing the prevention of risks of cross contamination.

## IV. INDICATIONS FOR USE

The EndoStream™ tubing is intended to provide irrigation via sterile water supply during gastrointestinal (GI) endoscopic procedures when used in conjunction with an irrigation pump.

## V. PREDICATE DEVICES

The EndoStream™ is designed as a disposable water irrigation tubing for irrigation pumps (direct connection between the endoscope and sterile water bottle via an irrigation pump.)

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

| **Predicate Device for the EndoStream™** | | |
|---|---|---|
| **Company** | **Predicate Device Name** | **FDA 510(k) Number** |
| Byrne Medical, Inc. | EndoGator | K092429 |
| EndoChoice, Inc. | EndoChoice Water Bottle Cap Irrigation System | K16482 |

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The EndoStream™ is substantially equivalent to the Byrne Medical, Inc. (EndoGator, K092429), and the EndoChoice, Inc. (EndoChoice Water Bottle Cap Irrigation System, K161482)

| Characteristic Compared | Our Device | Predicate 1 | Predicate 2 |
|---|---|---|---|
| Manufacturer | Partnership Medical, Ltd | Byrne Medical, Inc. | EndoChoice, Inc. |
| Device | EndoStream™ | EndoGator | EndoChoice Water Bottle Cap Irrigation System |
| 510(k) Number | - | K092429 | K161482 |
| Indication | The EndoStream ™ tubing is intended to provide irrigation via sterile water supply during gastrointestinal (GI) endoscopic procedures when used in conjunction with an irrigation pump. | Same | Same |
| Product Code/Class | OCX | OCX | OCX |

| Characteristic Compared | Our Device | Predicate 1 | Predicate 2 |
|---|---|---|---|
| Principle of Operation | Connects to a peristaltic pump to either the endoscopes auxiliary channel to allow flushing of water | Identical | Identical |
| Difference | None | None | None |
| Materials of Construction | Per section 16 | Identical | Identical |
| Sterilization | Ethylene Oxide | Ethylene Oxide | Ethylene Oxide |

VII. PERFORMANCE DATA

The following performance testing was completed (per respective standards).

- Sterilization Validation (ISO 11135)
- Shelf-Life / Aging Testing (ASTM 1980)
    - Dye Penetration
    - Seal Strength Testing
    - Visual Seal

Biocompatibility:

The materials used were tested for biocompatibility per ISO 10993. The tests performed were for cytotoxicity, Intracutaneous Irritation Test and Sensitization.

The EndoStream™ product was also test to demonstrate functionality and performance integrity.

VIII. CONCLUSIONS

Partnership Medical Limited considers the EndoStream™ 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.