April 6, 2020

KeyMed (Medical and Industrial Equipment) Ltd.
% Mary Anne Patella
Senior Specialist, Regulatory Affairs
Olympus Surgical Tech America - Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

Re: K193250
Trade/Device Name: Irrigation Tubing with CO2 or Air
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: February 26, 2020
Received: February 28, 2020

Dear Mary Patella:

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 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)*
K193250

Device Name
Irrigation Tubing with CO2 or Air

Indications for Use *(Describe)*
The Irrigation Tubing with CO2 or Air is intended for use up to 24 hours, to provide sterile water for irrigation through the auxiliary channel (via an irrigation flushing pump when used with an Auxiliary Channel Adaptor) and CO2 or air insufflation and lens flushing through the dual air-water channel (via a CO2 Gas Insufflator or Air pump supply) of compatible gastrointestinal/colono-endoscopes.

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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2 510(k) Summary of Safety and Effectiveness

2.1 General Information

Manufacturer:
KeyMed (Medical and Industrial Equipment) Ltd.
KeyMed House, Stock Road.
Southend-on-Sea, Essex, SS2 5QH, UK
Establishment Registration Number: 9611174

Official Correspondent:
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Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772
Phone: (508) 804-2771
Email: MaryAnne.Patella@olympus-osta.com

Establishment Registration Number: 3003790304

2.2 Device Identification

Proprietary name:	Irrigation Tubing with CO2 or Air
Device Classification name:	Endoscopes and Accessories
Regulation Medical Specialty:	Gastroenterology/Urology
Regulations Number:	21 CFR Part 876.1500
Regulatory class:	Class II
Product code:	OCX

2.3 Predicate Device

The proposed devices:

- MAJ-2207 Irrigation Tubing with CO2
- MAJ-2208 Irrigation Tubing with CO2
- MAJ-2209 Irrigation Tubing with Air
- MAJ-2210 Irrigation Tubing with Air

are considered substantially equivalent to legally marketed device of K102855, 21 CFR 876.1500:

- (100605) Universal Irrigation Solution Hybrid, Byrne Medical

No reference devices were used in this submission.

2.4 Product Description

The proposed device consists of four separate labelled tube set devices in total, two tube sets (MAJ-2207 & MAJ-2208) designed to be used with CO2 with differing bottle cap thread variants; and two tube sets (MAJ-2209 & MAJ-2210) designed to be used with Air with differing bottle cap thread variants to fit a variety of on the market branded disposable sterile bottles.

2.5 Indications for Use

The Irrigation Tubing with CO2/Air is intended for use for up to 24 hours, to provide sterile water for irrigation through the auxiliary channel (via an irrigation flushing pump when used with an Auxiliary Channel Adaptor) and CO2 or air insufflation and lens flushing through the dual air-water channel (via a CO2 Gas Insufflator or Air pump supply) of compatible gastrointestinal/colono-endoscopes.

2.6 Technological Characteristics

The Irrigation Tubing with CO2 or Air has the same intended use and technological characteristics as the predicate device Universal Irrigation Solution Hybrid, Byrne Medical (K102855) and any differences listed do not affect the criticality of intended use, safety or effectiveness of the device (See Table 2.1: Summary of Technological Characteristics).

Technological Characteristics	Subject Device:	Predicate Device
Sterilisation Type	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Length	1550nn	1840mm
Type of connection	Cap connection to sterile water bottles (1000ml).	Cap connection to sterile water bottles (1000ml).
Duration of Use	24 hours	24 hours
Number of patients	Multi Patient	Multi Patient

Table 2.1: Summary of Technological Characteristics

2.7 Substantial Equivalence

Substantial equivalence is demonstrated by acknowledged verification/validation methodologies. The subject devices have equivalent technology, performance, dimensions and materials. The differences to the predicate device Universal Irrigation Solution Hybrid are:

- Subject devices market seperate Air and CO2 use variant.
- Air variant does not include unneccessary (4th line) CO2 inlet line.
- Optimised lengths to reduce the risk of trip hazard with excessive lengths.
- Bottle cap component is two part rotatable cap.
- New PVC materials which contains less than 1% DEHP.

2.8 Performance Data

The following performance data were provided in support of the substantial equivalence determination. All standards applied are FDA recognised international standards.

2.8.1 Biocompatibility testing

The proposed Irrigation Tubing with CO2 or Air devices have an indirect contact with the patient delivering intermittent fluid or gas through the tubes into the gastrointestinal tract. Biocompatibility evaluation can be found in the following sub sections.

2.8.2 Electrical safety and electromagnetic compatibility (EMC)

The proposed Irrigation Tubing with CO2 or Air does not contain any electronic components and is electrically inert and therefore EMC is not required.

2.8.3 Thermal Safety

The proposed Irrigation Tubing with CO2 or Air does not contain any electronic components and is electrically inert and therefore thermal safety is not required.

2.8.4 Animal and Clinical Studies

Clinical and animal studies were not necessary.

2.8.5 Software

The proposed Irrigation Tubing with CO2 or Air does not contain any software.

2.8.6 Performance Testing Bench

To demonstrate substantial equivalence KeyMed considered the following subject devices performance aspects in regards to the predicate device within the design verification and validation:

1. Verification tests on flow performances were compared directly between the subject and predicate device through benchtop testing.
2. Usability evaluation compared the handling, setup and operation directly between the subject and predicate device.

Basic safety and performance testing was performed in accordance with IEC standards in accordance with the design verification plan. Usability of the user interface was also assessed according to the design validation plan and IEC 62366-1:2015. In addition, verification and comparison bench studies were conducted to evaluate the functional performance.

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971:2012.

2.8.7 Reprocessing

The proposed Irrigation Tubing with CO2 or Air are for use up to 24 hours, and are for multiple patients, with no reprocessing required between patients. This is thanks to the MAJ-1652 Auxiliary Channel Adaptor, which is intended for single-patient use and has a one way valve which acts as backflow prevention feature.

2.8.8 Applied standards

Standard No.	Standard Title	FDA-Recognition no + date
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2-258 01/14/2019
ISO 10993-5:2009	Biological Evaluation of medical devices Part 5: Test for in vitro cytotoxicity	2-245 12/23/2016
ISO 10993-7:2008	Biological Evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	14-408 01/30/2014
ISO 10993-10:2010	Biological Evaluation of medical devices Part 10: Tests for Irritation and Skin Sensitization	2-174 07/26/2016
ISO 22442-1:2015	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	15-45 06/27/2016
ISO 11135-1:2014	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices	14-452 04/04/2016
ISO 11607-1:2017	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-454 01/27/2015
IEC 60417:2002 DB	Graphical symbols for use on equipment - 12-month subscription to regularly updated online database comprising all graphical symbols published in IEC 60417	5-102 06/15/2016
ISO 7000:2014	Graphical symbols for use on equipment -- Registered symbols	5-103 06/15/2016
ASTM F88 / F88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials	14-482 06/27/2016
ASTM F2096 - 11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	14-359 01/15/2013
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	14-484 06/27/2015
ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications	5-115 07/15/2019

Table 2.2: Applied standards

2.9 Conclusion

The performance data support the safety of the devices and demonstrate that the subject devices comply with the recognised standards as specified.
In summary, we believe the proposed Irrigation Tubing with CO2 or Air is substantially equivalent with the predicate device with respect to the general design approach, function, and the intended use. The proposed Irrigation Tubing with CO2

or Air raises no new concerns of safety or effectiveness when compared to the predicate device.