K100803
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510(k) Summary
(per 21 CFR 807.92)
Olympus Flushing Pump OFP-1

APR 22 2010

1. SPONSOR/APPLICANT

KeyMed (Medical & Industrial) Ltd.
Stock Road
Southend-On-Sea
Essex SS2 5QH
United Kingdom

2. CONSULTANT/CONTACT

Medical Device Consultants, Inc.
11440 West Bernardo Drive, Suite 300
San Diego, CA 92127
Telephone: 858-753-1961
Facsimile: 858-753-1962

Primary Contact: Ron Warren

3. DEVICE NAME

Proprietary Name:	Olympus Flushing Pump OFP-1
Common/Usual Name:	Endoscopic Flushing or Lavage Pump
Classification Name:	Endoscope and accessories

4. DEVICE CLASSIFICATION

An endoscope and accessories has been classified by the Gastroenterology/Urology Devices Panel as a Class II device per 21 CFR 876.1500, Product Code FEQ.

5. PREDICATE DEVICES

The predicate device is the Olympus OFP cleared on May 12, 2000 under K000948.

6. DEVICE DESCRIPTION

The Olympus Flushing Pump is peristaltic pump which facilitates direct washing of debris from the observation site during endoscopic examinations. The peristaltic pump

and associated tubing allow irrigation water to be controlled and directed to the observation site to remove blood, faeces or other organic matter that may be obstructing the endoscopic view.

7. INTENDED USE/INDICATIONS FOR USE

The Olympus Flushing Pump OFP is indicated for use during GI endoscopy, when blood, faeces or other organic matter obscure the endoscopic view, to wash the site being visualized.

8. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject of this Special 510(k) is a modification of the Olympus Flushing Pump OFP that was previously cleared on May 12, 2000 under Premarket Notification Number K000948. The subject of this Special 510(k) is a modification of the Auxiliary Water Irrigation Tube used in the OFP. The modifications are:

- A change in the component material of the tubing from Tygon (proprietary polyvinyl chloride) to polyvinyl chloride (PVC) - both materials are Class VI biocompatible.
- Provision of the tubing in a sterilized package (previous tubing was supplied non-sterile)

No modification is being made to the OFP system hardware or other components. The change to the water irrigation tubing is being made to provide greater customer convenience by offering a sterilized irrigation ready for off-the-shelf use, and for manufacturing efficiencies by using a tubing material in use for other KeyMed systems.

9. PERFORMANCE TESTING

Validation activities to support the use of the modified Auxiliary Water Irrigation Tube consisted of four main elements:

- Biocompatibility testing of the PVC tubing
- Validation of the Gamma Sterilization Process
- Validation of the Irrigation Tube Packaging
- Performance testing of the new irrigation tube

Testing of the modified irrigation tube has demonstrated that the OFP fulfills prospectively defined performance criteria and that the modified system meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

KeyMed (Medical & Industrial) Ltd.
% Mr. Ronald S. Warren, RAC
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
11440 W. Bernardo Drive, Suite 300
SAN DIEGO CA 92127

APR 22 2010

Re: K100803
Trade/Device Name: Olympus Endoscopic Flushing Pump Model OFP-1
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: March 19, 2010
Received: March 24, 2010

Dear Mr. Warren:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100803

Device Name: Olympus Endoscopic Flushing Pump Model OFP-1

Indications for Use:

The Olympus Flushing Pump OFP is indicated for use during GI endoscopy, when blood, faeces or other organic matter obscure the endoscopic view, to wash the site being visualized.

Prescription Use X AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100803