DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OLYMPUS OPT-ELECTRONICS CO., LTD.
% Ms. Tina Steffanie-Oak
Senior R.A. Analyst
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K031256
Trade/Device Name: XSIF-1TQ140A Small Intestinal Videoscope
XBO1-681-26 Stylet
ST-S1 Splinting Tube
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDA
Dated (Date on orig SE ltr): April 18, 2003
Received (Date on orig SE ltr): April 24, 2003

Dear Ms. Steffanie-Oak,

This letter corrects our substantially equivalent letter of July 23, 2003.

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. 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); 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 contact 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. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number(if known): K031256

Device Name: XSIF-1TQ140A SMALL INTESTINAL VIDEOSCOPE
XBO1-681-26 STYLET
ST-S1 SPLINTING TUBE

Indications for Use:

XSIF-1TQ140A SMALL INTESTINAL VIDEOSCOPE

This instrument has been designed to be used with the OLYMPUS EVIS Video System Center, EVIS Universal Light Source, Documentation Equipment, Video Monitor, Endo-Therapy Accessories (such as a Forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the small intestine.

XBO1-681-26 STYLET

This product has been designed to increase stiffness of insertion part of Olympus small intestinal videoscope XSIF-1TQ140A by inserting to the endoscope biopsy channel.

ST-S1 SPLINTING TUBE

This product has been designed to be used with the XSIF-1TQ140A for endoscopy within the small intestinal tract. This product is intended to facilitate insertion of the scope by straightening from the esophagus through stomach to descending part of duodenum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031256

(Optional Format 1-2-96)

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SMDA 510(k) SUMMARY

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant: OLYMPUS OPT-ELECTRONICS CO., LTD.
(New Company Name: AIZU OLYMPUS CO., LTD)
Address: 500 Aza Muranishi Ooaza Niidera, Monden-machi
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Establishment Registration No.: 9610595

2. Submission Correspondent: Tina Steffanie-Oak
Title: Senior R.A. Analyst
OLYMPUS AMERICA INC.
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Telephone: 631-844-5477
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E-mail address: Tina.Steffanie-Oak@olympus.com
Establishment Registration No.: 2429304

3. Initial Impoter: Olympus America Inc.
Address: Two Corporate Center Drive, Melville, NY 11747-3157
Establishment Registration No.: 2429304

B. DEVICE IDENTIFICATION

1. Common/Usual Name
SMALL INTESTINAL VIDEOSCOPE

2. Device Name
SIF-1TQ140A SMALL INTESTINAL VIDEOSCOPE

3. Classification Name

CFR Number	Classification Name	Class	Product Code
876.1500	Endoscopes and accessories	II	78-KOG

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C. IDENTIFICATION OF LEGALLY MARKETED DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

The following listed devices are considered as predicate devices in consideration of their characteristics, and the following table shows their regulatory histories.

Model	510(k)#	Manufacturer	Class	Product Code
SIF-B Small Intestinal Fiberscope	Preamendment Device	Olympus Optical Co., Ltd.	II	78-KOG
SIF-SW Sonde-type Small Intestinal Fiberscope	#K904800	Olympus Optical Co., Ltd.	II	78-KOG
EVIS EXERA Colonovideoendoscopes	#K001241	Olympus Optical Co., Ltd.	II	78-KOG
PR-2B(Cannula with Stylet) for EVIS-200 System	#K931154	Olympus Optical Co., Ltd.	II	77-EOQ
ST-C6/C8 Splinting Tube for EVIS-140 Series Scopes	#K954451	Olympus Optical Co., Ltd.	II	78-FDS

D. DEVICE DESCRIPTION

1. Summary

The subject device, the XSIF-1TQ140 is basically identical to the preamendment device, the SIF-B except that the mechanical structure of variable stiffness has been added and the imaging system has been changed from fiber to CCD.

While the mechanical structure of variable stiffness (Refer to Attachment 2, "Flexibility Adjustment Function") and the CCD imaging system for use in the small intestine are considered new technologies, these features are identical to those of another predicate device, the EVIS EXERA Colonovideoendoscopes (#K001241). Any new insertion method and techniques in consequence of the added mechanical structure of variable stiffness are not considered. A variable stiffness enteroscope enhances insertion depth compared to the conventional enteroscope with or without overtube. The mechanical structure of variable stiffness facilitates insertion of this scope into the small intestine (Refer to Appendix-3, "Clinical Literature").

By changing the imaging systems from fiber to CCD, this scope shows more excellent images than the SIF-B. Since the optical system of the subject device is equivalent to that of the predicate device, the CF-Q160AL (#K001241), it does not affect the safety and efficacy for diagnoses and treatments.

In conclusion, the subject device is substantially equivalent to the predicate devices. A comparison table of the subject device and predicate devices is found in Attachment 1.

2. Design

XSIF-1TQ140A has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1and IEC60601-2-18.

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3. Materials

All the patient contacting materials used in this endoscope and ancillary equipment are identical materials that have been cleared in the past 510(k) submissions. And all materials have been confirmed with ISO 10993-1.

4. Intended Use of the device

This instrument has been designed to be used with the OLYMPUS EVIS Video System Center, EVIS Universal Light Source, Documentation Equipment, Video Monitor, Endo-Therapy Accessories (such as a Forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the small intestine.

5. Summary including conclusion drawn form Non-clinical Tests

When compared to the preamendment/predicate device, XSIF-1TQ140A does not incorporate any significant changes in the intended use, method of operation, material, or designed that could affect the safety effectiveness. Therefore the clinical data is not necessary for its evaluation of safety and efficacy.