DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 15, 2016

Olympus Medical Systems Corp.
% Sheri Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610

Re: K143153
Trade/Device Name: EVIS EXERA II Duodenovideoscope Olympus TJF Type Q180V
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT, NWB
Dated: December 8, 2015
Received: December 11, 2015

Dear Sheri Musgnung,

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143153

Device Name
EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q180V

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the duodenum.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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510(k) SUMMARY
EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q180V

January 6, 2016

I. General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No: 8010047
■ Official Correspondent:	Sheri L. Musgnung Manager, Regulatory Affairs Olympus Corporation of the Americas 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610, USA Phone: 484-896-3147 FAX: 484-896-7128 Email: sheri.musgnung@olympus.com
■ Manufacturer:	AIZU OLYMPUS CO., LTD. 500 Aza Muranishi Ooaza-Iidera Monden-cho Aizuwakamatsu-Shi Fukushima, JAPAN 965-8520 Registration Number: 9610595

II. Device Identification

■ Device Trade Name:	EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q180V
■ Common Name:	Duodenoscope
■ Regulation Number:	876.1500
■ Regulation Name:	Endoscope and Accessories
■ Regulatory Class:	II

- Classification Panel: Gastroenterology and urology
- Product Code: FDT; Duodenoscope, accessories, flexible/rigid
  NWB; Endoscope, accessories, narrow band spectrum

III. Predicate Device Information

- **Device Trade Name:** XTJF Q160VF1 DUODENOVIDEOSCOPE
- **510(k) Number** K080403
- **Decision Date** 05/20/2008
- **Manufacturer** AIZU OLYMPUS CO., LTD

IV. Device Description

The EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q180V is a flexible video endoscope used for endoscopic diagnosis and treatment within the duodenum. The device has a sealed elevator wire channel and a dual guidewire locking mechanism.

V. Indications for Use

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the duodenum.

VI. Comparison of Technological Characteristics

The difference between the subject device and the predicate device is as follows;

- Consists of a sealed elevator wire channel
- Consists of a dual guidewire locking mechanism
- Modifications to the device's labeled reprocessing procedure
- Addition of recommended combination of equipment and accessories
- Physical dimensions of components at distal end tip

VII. Summary of non-clinical testing

The differences of technological characteristics between the predicate device and the subject device are confirmed that they are substantially equivalent through the following tests and standards.

- Performance testing and design analysis was carried out to demonstrate the safety and effectiveness of the sealed elevator wire channel and the dual guidewire locking mechanism.

- The validation test on the reprocessing is performed in accordance with the FDA guidance "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance - April 1996". The FDA guidance “Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – May 2011” is also taken into consideration.

- Biocompatibility testing is performed in accordance with the FDA Guidance, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” dated on May 1 1995.

- The software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

- Electromagnetic compatibility, electric safety, and thermal safety had been confirmed.

- Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

- The following standards have been applied to the TJF-Q180V.
  - IEC 60601-1
  - IEC 60601-1-2
  - IEC 60601-2-18
  - ISO 11135-1
  - ISO 10993-7
  - ISO 10993-1
  - ISO 10993-5
  - ISO 10993-10
  - ISO 14971

VIII. Conclusion

Based on the 510(k) submission data, Olympus believes that the subject device and the predicate device selected are substantially equivalent and do not change the fundamental scientific technology and indications for use.