January 17, 2020

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

Re: K193182
Trade/Device Name: Evis Exera III Duodenovideoscope Olympus TJF-Q190V
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT, NWB, OCX
Dated: November 15, 2019
Received: November 18, 2019

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. 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)*
K193182

Device Name
EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.1 General Information

■ Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507
Establishment Registration No: 8010047

■ Official Correspondent:

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■ Manufacturing site:

Aizu Olympus Co., Ltd.,
500 Muranishi, Niidera, Monden-machi, Aizuwakamatsu-shi,
Fukushima 965-8520, Japan

5.2 Device Identification

■ Device Name	- EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V
■ Model Name	TJF-Q190V
■ Common Name	Duodenoscope and accessories
■ Regulation Number	876.1500
■ Regulation Name	Endoscope and Accessories
■ Regulatory Class	II
■ Product Code	FDT; Duodenoscope, Accessories, Flexible/Rigid NWB; Endoscope, accessories, narrow band spectrum

OCX; Endoscopic Irrigation/Suction System

■ Classification Panel Gastroenterology/Urology

5.3 PREDICATE DEVICE

Table 1 Predicate device on TJF-Q190V

Device name	510(k) Submitter	510(k) No.
EVIS EXERA II DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q180V	OLYMPUS MEDICAL SYSTEMS CORP.	K143153

5.4 DEVICE DESCRIPTION

EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V

The TJF-Q190V 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. The TJF-Q190V is compatible with Olympus system "Video System Center OLYMPUS CV-190 and XENON LIGHT SOURCE OLYMPUS CLV-190 (K112680)".

The subject device consists of flexible insertion section, control section and endoscope connector section with equipped CCD chip which delivers images.

The light from the light source travels through the light guide to the light guide lens at the distal end. The light source can offer both the white light for the normal observation and the narrow band imaging (NBI). The CCD chip transduces the incident light from the objective lens to electrical signal. The video processor transduces electrical signal to video signal.

There is an instrument channel entirely inside of the flexible insertion section. Endo Therapy accessories can be inserted through the instrument channel. A forceps elevator is located at the distal end of the insertion section to elevate EndoTherapy accessories for endoscopic treatment.

The TJF-Q190V consists of a single-use distal cover, MAJ-2315 which has been designed to be attached to OLYMPUS TJF-Q190V to cover the distal end of the insertion tube and around the forceps elevator. MAJ-2315 is to be discarded after clinical use.

The following new reprocessing accessory has also been designed for use with TJF-Q190V:

DISTAL END FLUSHING ADAPTER MAJ-2319

The MAJ-2319 was designed to flush the distal end of the endoscope with reprocessing fluids.

The MAJ-2319 can be attached to the distal end of the endoscope during the manual cleaning and disinfection process to flush the distal end with reprocessing fluids. The reprocessing fluid is flushed through the MAJ-2319 to the distal end using a syringe.

5.5 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.

5.6 Comparison of Technological Characteristics

Although there are some major differences including those described below, the technological characteristics of the TJF-Q190V are functionally equivalent to the predicate device, TJF-Q180V.

1) New removable SINGLE USE DISTAL COVER MAJ-2315 is introduced to the subject device compared to fixed distal cover of the predicate device. Design modifications were made around the forceps elevator to optimize the movement of the forceps elevator.

2) The reprocessing process of the subject device is modified from the predicate device due to the introduction of SINGLE USE DISTAL COVER MAJ-2315. This includes the use of a DISTAL END FLUSHING ADAPTER MAJ-2319.

5.7 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Sterilization/Shelf life testing

Sterilization/shelf life testing for the MAJ-2315 were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff,

"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Accelerated aging test for the MAJ-2315 was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. The real-time aging test for three-years will be performed to demonstrate longer stability and support the results of the accelerated aging test.

2) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing for the TJF-Q190V were conducted and documentation was provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

3) Biocompatibility testing

Biocompatibility testing for the TJF-Q190V and MAJ-2315 were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test

4) Software verification and validation testing

Software verification and validation testing for the TJF-Q190V were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

5) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the TJF-Q190V. The system complies with the AAMI ANSI ES60601-1: 2005/(R)2012 and A1:2012 and IEC 60601-2-18: Edition 3.0 2009-08 standards for safety and the IEC 60601-1-2: Edition 4: 2014-02 standards for EMC.

6) Performance testing - Bench

Bench testing for the TJF-Q190V and its accessories as listed below was conducted to ensure that the subject device performs as intended and meet design specifications. Device performance assessed the design requirements, and included process verification, design verification, and design validation.

- Thermal Safety test
- Mechanical durability test
- Performance testing for MAJ-2315
- Photobiological safety test
- Accidental Physical Impact testing on distal tip

7) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

8) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

9) Risk analysis

Risk analysis for the TJF-Q190V was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007 and the human factors validation was conducted in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices". The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the TJF-Q190V raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.