May 11, 2022

Olympus Medical Systems Corp.
% Wendy Perreault, Regualtory Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway,
P.O. Box 610
Center Valley, PA 18034-0610

Re: K220587
Trade/Device Name: Evis Exera III Duodenovideoscope Olympus TJF-Q190V
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT, NWB
Dated: February 25, 2022
Received: March 1, 2022

Dear Wendy Perreault:

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.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K220587

Device Name
EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Ql90V

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary: K220587

## 1. Company Information

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

- Official Correspondent: Wendy Perreault
  c/o Olympus Corporation of the Americas
  3500 Corporate Parkway
  P.O. Box 610
  Center Valley, PA 18034-0610
  Phone: 404.542.5854
  E-mail: wendy.perreault@olympus.com

- Manufacturing Site: Aizu Olympus Co., Ltd.,
  3-1-1 Niiderakita, Aizuwakamatsu-shi,
  Fukushima 965-8520, Japan

- Date Prepared: May 2, 2022

## 2. Product Information

- Trade Name: EVIS EXERA III DUODENOVIDEOSCOPE
  OLYMPUS TJF-Q190V

- Common Name: Duodenoscope and accessories

- Classification Name: Endoscope and Accessories

- Regulation Number: 876.1500

- Regulation Name: Endoscope and Accessories

- Regulatory Class: II
- Product Code(s): FDT (Duodenoscope, Accessories, Flexible/Rigid)
  NWB (Endoscope, accessories, narrow band spectrum)
- Classification Panel: Gastroenterology/Urology

## 3. Predicate Device

The subject device is equivalent to the predicate device listed below in **Table 1.**

**Table 1: Predicate device on TJF-Q190V**

| Device name | 510(k) Submitter | 510(k) No. |
|---|---|---|
| EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF TYPE Q190V | OLYMPUS MEDICAL SYSTEMS CORP. | K202661 |

## 4. Device Description

The EVIS EXERA III DUODENOSCOPE 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 a flexible insertion section, control section and endoscope connector section with equipped charge-coupled device (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 white light for normal observation and narrow band imaging (NBI). The CCD chip transduces the incident light from the objective lens to electrical signal. The video processor transduces the electrical signal to video signal.

There is an instrument channel located inside of the flexible insertion section. EndoTherapy 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.

A sterile, single-use Distal Cover (MAJ-2315) has been designed to be attached to the OLYMPUS TJF-Q190V to cover the distal end of the insertion tube and fit around the forceps elevator. MAJ-2315 is to be discarded after clinical use. MAJ-2315 and TJF-Q190V were previously cleared under 510(k)s K193182 and K202661.

## 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.

## 6. Comparison of Technological Characteristics

Compared to the predicate device, the changes are limited to design modifications to the sterile, single-use Distal Cover MAJ-2315 used with the TJF-Q190V and labeling updates.

There are no other changes to either the MAJ-2315 or TJF-Q190V devices, including changes to indications for use, conditions of use, compatible components and accessories to be marketed/used with the device, or patient-contacting materials. There are no changes to the device specifications for TJF-Q190V, including optical or electrical performance.

## 7. Summary of Non-clinical Performance Data

Verification/validation activities were performed subsequent to a risk assessment evaluation of the device modifications per the Olympus Quality Management System. Results of the following testing demonstrate that the changes to the Distal Cover MAJ-2315 do not adversely affect device performance:

- Performance Testing - Bench
- Sterilization Validation and Shelf-Life Testing
- Biocompatibility Evaluation
- Human Factors Evaluation

## 8. Summary of Clinical Performance Data

No clinical data were collected.

## 9. Conclusion

Based on the results of the comparison of the indications for use, technological characteristics, and performance testing of the subject and predicate device, the modified Distal Cover MAJ-2315 used with the TJF-Q190V duodenoscope raises no new issues of safety and effectiveness and the device is substantially equivalent to the predicate device and is as safe, as effective, and performs as well as or better than the predicate device.