September 17, 2021

Olympus Medical Systems Corp.
% Jon Gilbert
Regulatory Affairs Consultant for Olympus
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K201832
Trade/Device Name: ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET, GCJ, NWB
Dated: August 13, 2021
Received: August 16, 2021

Dear Jon Gilbert:

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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K201832

Device Name
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5

Indications for Use *(Describe)*
This instrument is intended to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

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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510(k) Summary

I. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
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Japan

■ Contact Person: Jon Gilbert
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■ Manufacturing site: Aizu Olympus Co., Ltd.,
500 Muranishi, Niidera, Monden-machi, Aizuwakamatsu-shi,
Fukushima 965-8520, Japan

Date Prepared: September 14, 2021

II. DEVICE IDENTIFICATION

■ Device Name: ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE
OLYMPUS LTF-S190-5

■ Common Name: VIDEOSCOPE

■ Regulation Number: 21 CFR 884.1720

■ Regulation Name: Gynecologic laparoscope and accessories

■ Regulatory Class: II

■ Product Code: HET; Laparoscope, Gynecologic (And Accessories)
GCJ; Laparoscope, General & Plastic Surgery
NWB; Endoscope, Accessories, Narrow Band Spectrum

■ Classification Panel: Obstetrics/Gynecology

III. PREDICATE DEVICE

Device name	510(k) Submitter	510(k) No.
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-190-10-3D	OLYMPUS MEDICAL SYSTEMS CORP.	K123365

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

■ **General Description of the subject device**

This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

■ **Principle of Operation**

The LTF-S190-5 is a video endoscope consisting of three parts: the control section, the insertion section, and the connector section. The device uses an objective lens and light guide lens for capturing images/videos from the distal end of the endoscope.

V. INDICATIONS FOR USE

ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5

This instrument is intended to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THEPREDICATE DEIVCE

The detailed comparison chart between subject device and predicate devices are as follows.

Item	Subject Device (SD)	Predicate Device (PD)
	LTF-S190-5	LTF-190-10-3D
Indications for Use	This instrument is intended to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy andendoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.	This instrument is intended to be used with Olympus video system center, light source, documentation equipment, 3D processor, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the thoracic and abdominal cavities including female reproductive organs. This instrument must not be used for observation or treatment of the heart and must not contact the heart or any area near the heart. In addition, this instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/ Repeat use	Repeat use	Repeat use
Sterile/ Non-sterile	Non-sterile	Non-sterile
Sterilization method	Ethylene oxide, Autoclave, Hydrogen peroxide (Sterrad 100S/ NX)	Ethylene oxide, Hydrogen peroxide (Sterrad NX)
Field of View	85°	80°
Direction of View	0° (Forward viewing)	0° (Forward viewing)
Depth of Field	18-100 mm	18-100 mm
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	2
Narrow Band Imaging observation	Available	Available
Insertion Tube Diameter	Distal end size: ø 5.4 mm Insertion tube outer Diameter (Maximum): ø5.4 mm	Distal end size: ø 10 mm Insertion tube outer Diameter (Maximum): ø 10 mm
Working Length	370 mm	370 mm
Channel inner diameter	No instrument channel	No instrument channel
Angulation Range	U/D:100°/100° R/L:100°/100°	U/D:100°/100° R/L:100°/100°

Item	Subject Device (SD)	Predicate Device (PD)
	LTF-S190-5	LTF-190-10-3D
Patient contacting material	Bending rubber: Fluoro Rubber Distal end/ Distal cover/ Insertion tube/ Pin: Stainless steel Glue: Epoxy Resin Lens: Glass	Bending rubber: Fluoro Rubber Distal end / Insertion tube: Stainless steel Glue: Epoxy Resin Lens: Glass
Duration and type of contact	External communicating device in contact with mucosal membranes, damaged mucosal membranes and tissue/bone/dentin. The contact duration is limited exposure (i.e. contact is up to 24 hours).	External communicating device in contact with mucosal membranes, damaged mucosal membranes and tissue/bone/dentin. The contact duration is limited exposure (i.e. contact is up to 24 hours).

The indications for use of the subject device do not raise different questions of safety and effectiveness when compared to the predicate device. The subject and predicate devices have the same intended use of providing visualization during thoracic and abdominal surgery, including the female reproductive organs. The differences in technological characteristics do not raise new questions of safety and effectiveness.

VII. PERFORMANCE DATA

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

1) Reprocessing validation testing

All reprocessing methods including the Sterilizer/Sterilization process were validated in accordance with the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued on March 17, 2015. The acceptance criteria were met.

2) Biocompatibility testing

Biocompatibility testing for the LTF-S190-5 final product was 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".

- Cytotoxicity Study Using the Colony Assay (ISO 10993-5:2009)
- Intracutaneous Study in Rabbits (ISO 10993-10:2010)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10:2010)
- Acute Systemic Toxicity Study in Mice (ISO 10993-11:2006)

- Rabbit Pyrogen Study (USP <151>, USP <37>)

The device was shown to be non-cytotoxic, non-irritating, non-sensitizing, not systemically toxic, and non-pyrogenetic.

3) Software verification and validation testing

Software verification and validation testing for the LTF-S190-5 was 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". The device met all requirements.

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LTF-S190-5. The system complies with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC. The device met all requirements.

5) Performance testing - Bench

Bench testing for the LTF-S190-5 as listed below was conducted to ensure that the subject device performs as intended and meet design specifications. Device performance was assessed the design requirements, and included process verification, design verification, and design validation. The device met all acceptance criteria.

- Thermal safety test
- Composite durability test
- Color (imaging) performance
- Photobiological Safety

VIII. CONCLUSIONS

The indications for use and technological characteristics of the LTF-S190-5 do not raise different questions of safety and effectiveness as compared to the predicate. The performance testing demonstrate that the subject device is as safe and effective as the predicate. Therefore, and the subject device is substantially equivalent to the predicate device.