April 3, 2020

Olympus Medical Systems Corp.
Lisa Boyle
Regulatory Affairs Specialist II
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K193026
Trade/Device Name: VISERA ELITE II VIDEO SYSTEM CENTER
OLYMPUS OTV-S300,
VISERA ELITE II VIDEO TELESCOPE
ENDOEYE 3D WA50080A, WA50082A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ, HET, GCM, FET, NWB
Dated: February 25, 2020
Received: February 28, 2020

Dear Lisa Boyle:

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,

for
Jason Roberts, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193026

Device Name
VISERA ELITE II VIDEO SYSTEM CENTER
OLYMPUS OTV-S300
VISERA ELITE II VIDEO TELESCOPE ENDOEYE 3D WA50080A, WA50082A

Indications for Use *(Describe)*

OLYMPUS OTV-S300

This video system center is intended to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.

VISERA ELITE II VIDEO TELESCOPE ENDOEYE 3D WA50080A, WA50082A

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 the female reproductive organs.
The device is also indicated for visualization during transanal and transvaginal natural orifice surgery.

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.

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April 3, 2020

510(k) Summary

5.1 GENERAL INFORMATION

- 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
  192-8507

- Contact Person: Lisa M. Boyle
  Olympus Corporation of the Americas
  3500 Corporate Parkway PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3676
  Fax: 484-896-7128
  Email: lisa.boyle@olympus.com

5.2.1 DEVICE IDENTIFICATION

■ Device Name	VISERA ELITE II VIDEO SYSTEM CENTER
■ Model Name	OLYMPUS OTV-S300
■ Common Name	ENDOSCOPIC IMAGING SYSTEM
■ Regulation Number	876.1500
■ Regulation Name	Endoscope and accessories
■ Regulatory Class	II
■ Product Code	FET; Endoscopic Video Imaging System/Component, Gastroenterology-Urology NWB; Endoscope, Accessories, Narrow Band Spectrum
■ Manufacturing site	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan

5.2.2 DEVICE IDENTIFICATION

■ Device Name	VISERA ELITE II VIDEO TELESCOPE ENDOEYE 3D
■ Model Name	WA50080A, WA50082A
■ Common Name	ENDOSCOPIC IMAGING SYSTEM
■ Regulation Number	876.1500
■ Regulation Name	Endoscope and accessories
■ Regulatory Class	II
■ Product Code	GCJ; Laparoscope, General & Plastic surgery HET; Laparoscope, Gynecologic (And Accessories) GCM; Endoscope, Rigid NWB; Endoscope, Accessories, Narrow Band Spectrum
■ Manufacturing site	Olympus Winter & Ibe GmbH Kuehnstr.61, 22045 Hamburg, Germany

5.3 PREDICATE DEVICE

- **Predicate device of OTV-S300**

Primary Predicate Device 1		
Device name	510(k) Submitter	510(k) No.
OLYMPUS OTV-S190	OLYMPUS MEDICAL SYSTEMS CORP	K111425
Additional Predicate Device 2		
Device name	510(k) Submitter	510(k) No.
OLYMPUS CLV-S190	OLYMPUS MEDICAL SYSTEMS CORP	K111425
Additional Predicate Device 3		
Device name	510(k) Submitter	510(k) No.
MAJ-Y0154	OLYMPUS MEDICAL SYSTEMS CORP	K123365

- **Predicate device of WA50080A, WA50082A**

Primary Predicate Device 1		
Device name	510(k) Submitter	510(k) No.
WA50050A/52A	Olympus Winter& Ibe GmbH	K190744

5.4 Recalled Predicate (K111788)

The Endoeye HD II Video Telescope cleared in predicate K111788 was the subject of a class II design related recall due to a damaged temperature sensor in the distal end of the endoscope. The issue has been successfully resolved and design changes have been cleared via K190744.

The installed heating element warms the distal tip to minimize or eliminate fogging of the lens during the procedure and aids in the prevention of endoscope removal to clean the lens due to fogging during a procedure. The ENDOEYE 3D does not include this feature.

5.5 DEVICE DESCRIPTION

- **General Description of the subject device**

The subject VISERA ELITE II consists of the following primary components:

- VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S300
- VISERA ELITE II VIDEO TELESCOPE ENDOEYE 3D WA50080A/ WA50082A

- **Principle of Operation**

The fundamental technology for the 3D function is identical to the predicate device.

A) VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S300

The subject device has both a processor function and light source function. By switching on the illumination lamp in the subject device, the device provides light through the endoscopes directly for endoscopic observation.

This device also constantly regulates the endoscopic image brightness from the video system center. The observation mode can be switched by the optical filter and LED extracting the specific wavelengths. There are two modes: WLI (White light imaging) mode for normal observation and NBI (Narrow-band imaging) mode for an optical image enhancement technology.

By driving the CCD equipped in the endoscopes, the images are transduced into electrical signals from the optical signals, and the subject device displays the endoscopic images on the monitors.

B) VISERA ELITE II VIDEO TELESCOPE ENDOEYE 3D WA50080A/ WA50082A

The subject devices are designed to transfer optical images from a body cavity via a lens system directly to an imager for further electrical signal transmission to a video processor. The video telescope is designed for examination, diagnosis, and visualization of treatment (treatment can only be performed by using endoscopic accessories in combination). For illumination of body cavities, the transfer of light from a supply unit to the body cavity is achieved by means of a light guide. The subject device, ENDOEYE 3D, is a design variant of the predicate ENDOEYE HD II video endoscope offering a 3D observation mode. The 3D effect enables the surgeon to perceive significant spatial information which is beneficial in terms of optimized speed, accuracy and precision of surgical procedures by users of all skill levels. It may also shorten the learning curve for surgical tasks.

The ENDOEYE 3D is used with a 3D video system and a 3D monitor with dedicated polarization glasses.
For laparoscopic applications, the video telescope is inserted via a trocar into the patient.
The ENDOEYE 3D is used with a video system center, light source and monitor to achieve its intended function.
In addition, the ENDOEYE 3D can be placed in compatible instrument trays for reprocessing.
The ENDOEYE 3D can provide an image with either white light or narrow band imaging.

5.6 INDICATIONS FOR USE

A) VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S300

This video system center is intended to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.

B) VISERA ELITE II VIDEO TELESCOPE ENDOEYE 3D WA50080A/ WA50082A

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 the female reproductive organs.
The device is also indicated for visualization during transanal and transvaginal natural orifice surgery.

The ENDOEYE 3D has the same indication of use as the predicate device except for the addition of the last sentence regarding visualization of transanal and transvaginal applications. This difference does not represent a different intended use.

5.7 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The VISERA ELITE II has the same technological characteristics and design as the predicate device except for the following new features:

-Integration of the video processor, light source, and 3D mixer (OTV-S300)
-New integrated video connector into one for 3D observation
-New LED construction
-No fog free function

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

OLYMPUS

Device Comparison Table of OTV-S300

	<Subject device> OTV-S300	<Primary Predicate device 1> OTV-S190	<Additional Predicate device 2> CLV-S190	<Additional Predicate device 3> MAJ-Y0154 3D PROCESSOR
510(k) Number	K193026	K111425	K111425	K123365
Rated voltage	100V AC 50/60Hz	100V AC 50/60Hz	100V AC 50/60Hz	100V AC 50/60Hz
Rated input	400VA	150VA	500A	100VA
Dimension (maximum)	W383×H199×D506 (mm)	W382×H91×D489 (mm)	W383×H162×D536 (mm)	W375×H91×D478 (mm)
Weight	19.3kg	8.8kg	14.9kg	7.7kg
AGC (Auto gain control)	Provided	Provided	Provided	Not provided
3D observation	Provided	Not provided	Not provided	Provided
Front panel (Operation)	Touch panel	Push button	Push button	Push button
Examination Lamp	LED	Not provided	Xenon lamp	Not provided
NBI	Provided	Provided	Provided	Not provided

OLYMPUS

Device Comparison Table of WA50080A, WA50082A

	<Subject device> WA50080A, WA50082A	<Predicate device 1> WA50050A/52A
510(k) Number	K193026	K190744 / K111788
Outer diameter of insertion tube (distal end)	WA50080A: max.10.07 mm WA50082A: max.10.20 mm	WA50050A: max. 5.45 mm WA50052A: max. 5.45 mm
Maximum working length	WA50080A: 330 mm WA50082A: 335 mm	WA50050A : 300.5 mm WA50052A : 303 mm
Direction of view (DOV)	WA50080A: 0° WA50082A: 30°	WA50050A: 0° WA50052A: 30°
NBI observation	Compatible	compatible
Field of view (FOV)	Both models: 67° ± 9°	Both models: 80.4° ± 8°
Depth of field	25 to 120 mm	21 to 200 mm
Type of CCD chip	Color CCD	Color CCD

	<Subject device> WA50080A, WA50082A	<Predicate device 1> WA50050A/52A
Number of CCD chip	2	1
2D function	Available	Available
3D function	The video telescope can transmit 2D images and 3D images to the video system center. The video telescope is equipped with a second image sensor inside the distal end to create 3D images that can be viewed on compatible video system centers and video monitors using compatible 3D glasses.	The video telescope can only transmit 2D images to the video system center. A 3D image sensor is not included and therefore; no 3D mode is offered.

All other technological characteristics of both the subject and predicate devices are identical. The differences in technological characteristics noted in the tables do not raise different questions of safety and effectiveness.

5.8 PERFORMANCE DATA

1) Risk analysis

Risk analysis for the OTV-S300 and the WA50080A/ WA50082A was conducted 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 the risk analysis assessment.

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

2) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing for the WA50080A/WA50082A 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 WA50080A/WA50082A 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:

- in vitro cytotoxicity
- irritation
- acute systemic toxicity
- material mediated pyrogenicity
- dermal sensitization test in guinea pigs - Magnusson and Kligman (M&K)

4) Software verification and validation testing

Software verification and validation testing for the he OTV-S300 and the WA50080A/WA50082A 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".

5) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted on the OTV-S300 and the WA50080A/WA50082A. 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.

6) Performance testing - Bench

Bench testing for the OTV-S300 and the WA50080A/WA50082A as listed below was conducted to ensure that the subject device performs as intended and meets design specifications.

[OTV-S300]

- Difference for Emergency Lamp (to ensure non-failure LEDs will function as emergency lights)
- NBI Observation
- Observation function
- Image Quality, including:
  - Brightness
  - Image Intensity
  - Color Performance
  - Signal to Noise ratio

-Usability

[WA50080A/ WA50082A]
- Real-use contamination
- Field of View
- Design Validation/Usability
- Evaluation of optical properties incl. comparison of optical system properties and image quality (predicate vs. subject devices)
- Thermal Safety
- Surfaces and Edges
- Working Length
- Evaluation of ghost effect
- Evaluation of still image
- Distortion
- Resolution
- Evaluation of performance after reprocessing
- Evaluation of illumination performance
- Mechanical stress resistance (bending/impact)

[OTV-S300 and WA50080A/ WA50082A]
- Photobiological safety

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.

5.9 CONCLUSIONS

Based on the performance testing the OTV-S300 and the WA50080A/WA50082A are as safe and effective and are substantially equivalent to the predicate device.