July 22, 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: K201200
Trade/Device Name: Visera Elite II Video System Center
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: April 28, 2020
Received: May 4, 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 R. 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)*
K201200

Device Name
VISERA ELITE II VIDEO SYSTEM CENTER

Indications for Use *(Describe)*
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.

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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OLYMPUS

Date Prepared: July 21, 2020

510(k) Summary

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

■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima 961-8061, Japan

2. DEVICE IDENTIFICATION

Trade Name	VISERA ELITE II VIDEO SYSTEM CENTER
Model	OTV-S300
Common Name	Endoscope and accessories
Regulation Number	21 CFR 876.1500
Regulation Name	Endoscope and accessories
Product Code	FET (endoscopic video imaging system/component, gastroenterology-urology)
Regulatory Class	II
Review Panel	Obstetrics/Gynecology

3. PREDICATE DEVICE/REFERENCE DEVICE

Predicate device

Predicate Device		
Device name	510(k) Submitter	510(k) No.
OLYMPUS OTV-S300 (VISERA ELITE II VIDEO SYSTEM CENTER)	OLYMPUS MEDICAL SYSTEMS CORP.	K193026

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

Reference device

Reference Device		
Device name	510(k) Submitter	510(k) No.
OLYMPUS OTV-S200 (VISERA ELITE II VIDEO SYSTEM CENTER)	OLYMPUS MEDICAL SYSTEMS CORP.	K190449

4. DEVICE DESCRIPTION

VISERA ELITE II VIDEO SYSTEM CENTER

■ Principle of operation and mechanism of action

The subject device is a video system center to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment used with endoscopes. The subject device is an update to the Visera Elite II Video System Center cleared under K193026 to add a 2D observation function.

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.
There are two modes: WLI (White light imaging) mode for normal observation and NBI (Narrow-band imaging) mode for enhanced optical image observation.

By driving the CCD equipped in an endoscope, the subject device displays an endoscopic images on a monitor.

5. INDICATIONS FOR USE

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.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The table below provides a comparison of the intended use and technological characteristics of the subject and predicate device.

Table: Comparison Table of the Subject and Predicate Device

	<Subject device> VISERA ELITE II VIDEO SYSTEM CENTER	<Predicate device > VISERA ELITE II VIDEO SYSTEM CENTER
Manufacturer	Olympus Medical Systems Corp	Olympus Medical Systems Corp
Indications for use	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.	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.
Rated voltage	100-120V AC 50/60Hz	100-120V AC 50/60Hz
Rated input	400VA	400VA
Dimension (maximum)	W383×H199×D506 (mm)	W383×H199×D506 (mm)
Weight	19.3kg	19.3kg
AGC (Auto gain control)	Provided	Provided
2D Observation	Provided	Not Provided
3D observation	Provided	Provided
Front panel	Touch panel	Touch panel

	<Subject device> VISERA ELITE II VIDEO SYSTEM CENTER	<Predicate device > VISERA ELITE II VIDEO SYSTEM CENTER
(Operation)		
Examination Lamp	LED	LED
Average lamp life	10000h	10000h
Emergency lamp	LED	LED
Average Emergency lamp life	10000h	10000h
NBI (Narrow band imaging)	Provided	Provided

The subject and predicate devices have identical Indications for Use statements and have the same intended use – for visualization during endoscopic surgical procedures. The subject and the predicate device have different technological characteristics. The predicate device has a 3D circuit board to generate 3D images whereas the subject device incorporates a circuit board that is able to generate both 3D and 2D images. The differences between the subject and predicate device do not raise different questions of safety and effectiveness.

7. PERFORMANCE DATA

To support the modification to the subject device to include a 2D observation function, the following design verification and validation activities were performed and summarized:

7.1 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted in accordance with ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009

for electrical safety and IEC 60601-1-2:2014 for EMC.

7.2 Software verification and validation testing

Software verification and validation for the subject device was conducted 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" (2005).

7.3 Performance testing - Bench

Bench testing for the subject device incorporating the 2D function was conducted to ensure that the subject device performs as intended and meets the appropriate design specifications, as follows.

- Image Quality
  - Brightness
  - Image Intensity
  - Color Performance
  - Signal to Noise ratio
- Video Latency

8. CONCLUSIONS

The results of the performance testing described above demonstrate that the VISERA ELITE II VIDEO SYSTEM CENTER is as safe and effective as the predicate device and supports a determination of substantial equivalence