August 30, 2019

Olympus Medical Systems Corp.
% Daphney Germain-Kolawole
Senior Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K190449
Trade/Device Name: Visera Elite II Video System Center,
Visera Elite II HD 3CMOS Autoclavable Camera Head,
Visera Elite II 3CMOS Camera Head
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FET, NWB
Dated: July 17, 2019
Received: July 19, 2019

Dear Daphney Germain-Kolawole:

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
Martha Betz, Ph.D.
Acting Assistant Division 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)*
K190449

Device Name
VISERA ELITE II VIDEO SYSTEM CENTER
VISERA ELITE IT HD 3CMOS AUTOCLAVABLE CAMERA HEAD
VISERA ELITE II HD 3CMOS CAMERA HEAD

Indications for Use *(Describe)*

VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S200
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 IT HD 3CMOS AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S200-XZ-EA
The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

VISERA ELITE II HD 3CMOS CAMERA HEAD OLYMPUS CH-S200-XZ-EB
The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and 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.

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Date Prepared: August 29, 2019

Section 5
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: Daphney Germain-Kolawole
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Center Valley, PA 18034-0610, USA
Phone: 484-896-5691
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■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima 961-8061, Japan

5.2 DEVICE IDENTIFICATION

5.2.1 OTV-S200

■ Device Name: VISERA ELITE II VIDEO SYSTEM CENTER

■ Model Name: OTV-S200

■ Common Name: Endoscopic Video Imaging System/Component

■ 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

■ Classification Panel: Gastroenterology/Urology

5.2.2 CH-S200-XZ-EA, CH-S200-XZ-EB

■ Device Name	VISERA ELITE II HD 3CMOS AUTOCLAVABLE CAMERA HEAD VISERA ELITE II HD 3CMOS CAMERA HEAD
■ Model Name	CH-S200-XZ-EA CH-S200-XZ-EB
■ Common Name	Endoscopic Video Imaging System/Component
■ 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
■ Classification Panel	Gastroenterology/Urology

5.3 PREDICATE DEVICE

5.3.1 OTV-S200

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S200	VISERA ELITE VIDEO SYSTEM CENTER OLYMPUS OTV-S190	K111425
	VISERA ELITE XENON LIGHT SOURCE OLYMPUS CLV-S190	K111425

5.3.2 CH-S200XZ-EA, CH-S200-XZ-EB

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
VISERA ELITE II HD 3CMOS AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S200-XZ-EA	AUTOCLAVABLE CAMERA HEAD OTV-Y0017	K102059
VISERA ELITE II HD 3CMOS CAMERA HEAD OLYMPUS CH-S200-XZ-EB	AUTOCLAVABLE CAMERA HEAD OTV-Y0017	K102059

5.4 DEVICE DESCRIPTION

5.4.1 OTV-S200

The OTV-S200 is intended to be used with OLYMPUS camera heads, endoscopes, monitors, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis, treatment, and video observation. The OTV-S200 has a light source and video processor function. The endoscope light guide cable is connected to the output socket on the subject device and the endoscope video connector or camera head is connected to video connector socket. The OTV-S200 emits light to the endoscope via the light guide cable and receives the electrical signal from the endoscope or camera head via the video connector. After processing, the OTV-S200 outputs endoscopic images on the monitor. The subject device provides white light imaging (WLI) and narrow band imaging (NBI). The OTV-S200 function is operated by a touch panel screen.

	<Subject device> OTV-S200	<Primary Predicate device 1> OTV-S190	<Additional Predicate device 2> CLV-S190
510(k) Number	-	K111425	K111425
Regulation number	884.1720	884.1720	884.1720
Regulatory Class	II	II	II
Product code	HET, FET,NWB, EOB, EOQ, FGB, GCJ	HET,EOB,EOQ, FGB,GCJ,NWB	HET,EOB,EOQ, FGB,GCJ,NWB
Manufacturer	Olympus Medical Systems Corp	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 has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment, and video observation.	This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

	<Subject device> OTV-S200	<Primary Predicate device 1> OTV-S190	<Additional Predicate device 2> CLV-S190
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Repeat use	Repeat use	Repeat use
Sterile/non-sterile	Marketed as non-sterile	Marketed as non-sterile	Marketed as non-sterile
Rated voltage	120V AC 50/60Hz	120V AC 50/60Hz	120V AC 50/60Hz
Rated input	400VA	150VA	500A
Dimension (maximum)	W383×H199×D506 (mm)	W382×H91×D489 (mm)	W383×H162×D536 (mm)
Weight	19.0kg	8.8kg	14.9kg
AGC(Auto gain control)	Provided	Provided	Provided
Front panel (Operation)	Touch panel	Push button	Push button
Examination Lamp	LED	Not provided	Xe lamp
NBI	Provided	Provided	Provided

5.4.2 CH-S200-XZ-EA, CH-S200-XZ-EB

The CH-S200-XZ-EA and CH-S200-XZ-EB have been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation. The CH-S200-XZ-EA and CH-S200-XZ-EB are compatible with Olympus rigid endoscopes to be used to observe various anatomical locations. The subject devices are constructed with a camera head (body), camera cable and video connector and connected to an endoscope by the lock ring on the camera head. Light is supplied from the video system center to the rigid endoscope via a light guide cable and emitted from the distal end of the endoscope. The objective lens on the distal end of the endoscope receives the light from the object and the light guide inside the endoscope transfers the light to the eyepiece and 3CMOS

(imager) inside the subject device. The imagers convert the light to an electrical signal and the signal is transferred to a video system center via the camera cable and video connector. Finally, an endoscopic image is outputted on the monitor after processing in the video system center. The subject devices provide white light imaging (WLI) and narrow band imaging (NBI). Zoom and focus are controlled by switches or rings on the camera head for the CH-S200-XZ-EA or CH-S200-XZ-EB, respectively. Three remote switches on the camera head provide operation of the video system center function by setting the functions prior to the procedure.

	<Subject device> CH-S200-XZ-EA	<Predicate device 1> OTV-Y0017 AUTOCLAVABLE CAMERA HEAD
510(k) Number	-	K102059
Regulation number	876.1500	876.1500
Regulatory Class	II	II
Product code	FET,NWB	FET,NWB
Manufacturer	Olympus Medical Systems Corp	Olympus Medical Systems Corp
Indications for use	The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.	This camera head has been designed to be used with the CV-180 EXERA II video system center or OTV-S7Pro VISERA Pro video system center, endoscopes, light sources, video monitors and other ancillary equipment for endoscopic diagnosis and treatment.
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Repeat use	Repeat use

	<Subject device> CH-S200-XZ-EA	<Predicate device 1> OTV-Y0017 AUTOCLAVABLE CAMERA HEAD
Sterile/non-sterile	Marketed as non-sterile	Marketed as non-sterile
Head dimension (mm)	W44 × H52 × L120	φ38mm×L106mm
NBI	Available	Available
Focus control	Electrical manual focus with focus control switches	Manual focus ring
Head weight	295g	215g
Image module	CMOS image sensor × 3	CCD image sensor × 1
Optical zoom	Provided	Not provided
Connector surface	Card edge connector	Card edge connector
Reprocessing	End user sterilized AUTOCLAVE/V-PRO/ STERRAD	End user sterilized AUTOCLAVE

	<Subject device> CH-S200-XZ-EB	<Predicate device 1> OTV-Y0017 AUTOCLAVABLE CAMERA HEAD
510(k) Number	-	K102059
Regulation number	876.1500	876.1500
Regulatory Class	II	II
Product code	FET,NWB	FET,NWB
Manufacturer	Olympus Medical Systems Corp	Olympus Medical Systems Corp
Indications for use	The camera head has been designed to be used with Olympus endoscopes,	This camera head has been designed to be used with the CV-180 EXERA

	<Subject device> CH-S200-XZ-EB	<Predicate device 1> OTV-Y0017 AUTOCLAVABLE CAMERA HEAD
	video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.	II video system center or OTV-S7Pro VISERA Pro video system center, endoscopes, light sources, video monitors and other ancillary equipment for endoscopic diagnosis and treatment.
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Repeat use	Repeat use
Sterile/non-sterile	Marketed as non-sterile	Marketed as non-sterile
Head dimension (mm)	W44 × H49 × L113	φ38mm×L106mm
NBI	Available	Available
Focus control	Electrical manual focus with focus control switches	Manual focus ring
Head weight	220g	215g
Image module	CMOS image sensor × 3	CCD image sensor × 1
Optical zoom	Provided	Not provided
Connector surface	Card edge connector	Card edge connector
Reprocessing	End user sterilized V-PRO/STERRAD	End user sterilized AUTOCLAVE

5.5 INDICATIONS FOR USE

VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S200

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 HD 3CMOS AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S200-XZ-EA

The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

VISERA ELITE II HD 3CMOS CAMERA HEAD OLYMPUS CH-S200-XZ-EB

The camera head has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

5.6.1 OTV-S200

The OTV-S200 has the same technological characteristics and design as the predicate device except for the following new features:

- Integration of the video processor and light source
- New LED construction

5.6.2 CH-S200-XZ-EA, CH-S200-XZ-EB

The CH-S200-XZ-EA and CH-S200-XZ-EB have the same technological characteristics and design as the predicate device except for the following new features:

- Adoption of 3CMOS

All other technological characteristics of both the subject and predicate devices are identical. Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

5.7 PERFORMANCE DATA

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

1) **Reprocessing validation testing**
   Reprocessing instruction and reprocessing method validation testing for the CH-S200-XZ-EA and CH-S200-XZ-EB 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".

2) **Software verification and validation testing**
   Software verification and validation testing for the OTV-S200 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".

3) **Electrical safety and electromagnetic compatibility (EMC)**
   Electrical safety and EMC testing were conducted on the OTV-S200, CH-S200-XZ-EA and CH-S200-XZ-EB. The subject devices comply 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.

4) **Performance testing - Bench**
   Bench testing for the OTV-S200, CH-S200-XZ-EA and CH-S200-XZ-EB as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

   - Difference for Emergency Lamp
   - NBI Observation
   - Image Quality
   - Photobiological safety
   - NBI Color Adjustment
   - Function of Switching of the "iris area"
   - Laser mode
   - Confirmation of Full HD image
   - FOV

5) **Performance testing - Animal**
   No animal study was performed to demonstrate substantial equivalence.

6) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

7) Risk analysis

Risk analysis for the OTV-S200, CH-S200-XZ-EA and CH-S200-XZ-EB 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 this risk analysis assessment.

The following voluntary standards to comply with have been applied to the OTV-S200, CH-S200-XZ-EA and CH-S200-XZ-EB, respectively:

OTV-S200

- AAMI / ANSI ES 60601-1
- IEC 60601-1-2
- IEC 60601-2-18
- ISO 14971
- IEC 62304

CH-S200-XZ-EA

- AAMI / ANSI ES 60601-1
- IEC 60601-1-2
- IEC 60601-2-18
- ISO 14971
- ISO 17665-1
- ISO 14937

CH-S200-XZ-EB

- AAMI / ANSI ES 60601-1
- IEC 60601-1-2
- IEC 60601-2-18
- ISO 14971
- ISO 14937

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the OTV-S200, CH-S200-XZ-EA and CH-S200-XZ-EB raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.