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

July 17, 2020

Re: K200542
Trade/Device Name: Visera Elite II Xenon Light Source, Telescope IR/Telescope Ultra, Visera Elite II Video System Center, HD 3CMOS Autoclavable Camera Head, HD 3CMOS Camera Head
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN, NWB, GCJ, HET, FET
Dated: June 19, 2020
Received: June 19, 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,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K200542

Device Name
VISERA ELITE II Infrared Imaging System

Indications for Use *(Describe)*

[VISERA ELITE II Infrared Imaging System]
The VISERA ELITE II Infrared Imaging System is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. The VISERA ELITE II Infrared Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the VISERA ELITE II Infrared Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization.

[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 XENON LIGHT SOURCE OLYMPUS CLV-S200-IR]
The light source has been designed to be used with Olympus endoscopes, video system centers, light guide cables, and other ancillary equipment for endoscopic observation through visible and near-infrared fluorescence imaging with fluorescence agent.

[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.

[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.

[TELESCOPE IR/ULTRA WAIR500A,WAIR530A,WAIR100A,WAIR130A]
These endoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal natural orifice surgery. In combination with a compatible infrared imaging system, the telescope allows for fluorescence imaging.

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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K200542

Date Prepared: July 16, 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
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Center Valley, PA 18034-0610, USA
Phone: 484-896-3676
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Email: lisa.boyle@olympus.com

5.2 DEVICE IDENTIFICATION

5.2.1 VISERA ELITE II Infrared Imaging System

■ Device Name: VISERA ELITE II Infrared Imaging System

■ Model Name: [System components]
- VISERA ELITE II XENON LIGHT SOURCE OLYMPUS CLV-S200-IR
- TELESCOPE IR WAIR100A, WAIR130A
- TELESCOPE ULTRA WAIR500A,WAIR530A
- VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS OTV-S200
- HD 3CMOS AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S200-XZ-EA
- HD 3CMOS CAMERA HEAD OLYMPUS CH-S200-XZ-EB
- Indocyanine Green

■ Common Name: -

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class II
■ Product Code -

■ Classification Panel General & Plastic Surgery

■ Manufacturing site: -

5.2.2 CLV-S200-IR

■ Device Name VISERA ELITE II XENON LIGHT SOURCE

■ Model Name CLV-S200-IR
■ Common Name Endoscopic Video Imaging System/Component

■ Regulation Number 876.1500

■ Regulation Name Endoscope and accessories

■ Regulatory Class II
■ Product Code OWN; Confocal optical imaging
NWB; Endoscope, Accessories, Narrow Band Spectrum

■ Classification Panel General & Plastic Surgery

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

5.2.3 WAIR100A, WAIR130A, WAIR500A, WAIR530A

■ Device Name TELESCOPE “ULTRA”
TELESCOPE “IR”

■ Model Name WAIR100A,WAIR130A,WAIR500A,WAIR530A
■ Common Name Laparoscopes

■ Regulation Number 876.1500
884.1720

■ Regulation Name Endoscope and accessories
Gynecologic laparoscope and accessories

■ Regulatory Class II
■ Product Code GCJ; Laparoscope, general & plastic surgery
HET; Laparoscope, gynecologic (and accessories)
■ Classification Panel General & Plastic Surgery

■ Manufacturing site:	Olympus Winter & Ibe GmbH Kuehnstr.61, 22045 Hamburg, Germany

5.2.4 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	OWN; Confocal optical imaging FET; Endoscopic Video Imaging System/Component, Gastroenterology-Urology NWB; Endoscope, Accessories, Narrow Band Spectrum
■ Classification Panel	General & Plastic Surgery
■ Manufacturing site:	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan

5.2.5 CH-S200-XZ-EA/ CH-S200-XZ-EB

■ Device Name	HD 3CMOS AUTOCLAVABLE CAMERA HEAD 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	OWN; Confocal optical imaging

FET; Endoscopic Video Imaging System/Component, Gastroenterology-Urology
NWB; Endoscope, Accessories, Narrow Band Spectrum

■ Classification Panel — General & Plastic Surgery

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

5.3 PREDICATE DEVICE

5.3.1 CLV-S200-IR

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
VISERA ELITE II XENON LIGHT SOURCE OLYMPUS CLV-S200-IR	Karl Storz Endoscopic ICG Imaging System	K152583

5.3.2 WAIR100A, WAIR130A, WAIR500A, WAIR530A

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
TELESCOPE IR WAIR100A, WAIR130A	WA4KL100/WA4KL130	K150633
TELESCOPE ULTRA WAIR500A,WAIR530A	WA4KL500/WA4KL530	

5.3.3 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 II VIDEO SYSTEM CENTER OLYMPUS OTV-S200	K190449

5.3.4 CH-S200-XZ-EA/ CH-S200-XZ-EB

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
HD 3CMOS AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S200-XZ-EA	HD 3CMOS AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S200-XZ-EA	K190449
HD 3CMOS CAMERA HEAD OLYMPUS CH-S200-XZ-EB	HD 3CMOS CAMERA HEAD OLYMPUS CH-S200-XZ-EB	K190449

5.4 REFERENCE DEVICE

5.4.1 CLV-S200-IR

Reference Device	Predicate Device 510(k) No.
PINPOINT Endoscopic Fluorescence Imaging System	K161792
daVinci Firefly Imaging System	K141077

5.4.2 WAIR100A, WAIR130A, WAIR500A, WAIR530A

Reference Device	Reference Device 510(k) No.
KARL STORZ Endoscopic ICG Imaging System	K152583
KARL STORZ Endoscopic ICG Imaging System	K162882
KARL STORZ Endoscopic ICG Imaging System	K171238

5.5 DEVICE DESCRIPTION

The subject devices OTV-S200, CH-S200-XZ-EA, and CH-S200-XZ-EB were cleared in 510(k) K190449. After clearances, no technological modification for the subject devices were made. Therefore, the above devices have been omitted from the device description in this pre-market notification.

5.5.1 CLV-S200-IR

This device consists of the source circuit, the control circuit, the illumination lamp, and the optical filter. The control circuit connects to the diaphragm to regulate the light intensity, the source circuit supplies the power to the illumination lamp, the operation panel and the rear panel. By switching on the illumination lamp, this device provides the light for endoscopic observation. This device regulates the endoscopic image brightness constantly from the video system center. The observation mode can be switched by the optical filter extracting the specific wavelengths.

	Subject Device CLV-S200-IR	Primary Predicate Device 1	Reference Device 1	Reference Device 2
510(k) Number	K200542	K152583	K161792	K141077
Regulation number	21 CFR part 876.1500	21 CFR part 876.1500	21 CFR part 876.1500	21 CFR part 876.1500
Regulatory Class	II	II	II	II
Product code	OWN, NWB	OWN	GCJ; IZI	NAY, GCJ, IZI

	Subject Device CLV-S200-IR	Primary Predicate Device 1	Reference Device 1	Reference Device 2
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP	Karl Storz Endoscopy-America, Inc.	Novadaq Technologies Inc.	Intuitive Surgical Incorporated
ICG agent	Co package	Co package	Co package	Co package
Light source	Xenon	Xenon	Laser	Laser
3D image	Not available	Not available	Not available	Available
WLI*	Available	Available	Available	Available
NBI*	Available	Not available	Not available	Not available
IR*	Available	Available	Available	Available

* White Light Imaging (WLI), Narrow band imaging (NBI), Infrared Imaging (IR)

5.5.2 WAIR100A, WAIR130A, WAIR500A, WAIR530A

The “IR” Telescopes are rigid endoscopes. An image relay system of rod lenses transmits the endoscopic image. A bundle of optical fibers transmits light from an external light source to illuminate the endoscopic image.

The “IR” Telescopes are delivered non-sterile. They are reusable and fully autoclavable. Before the first and each subsequent use of the device, it must be inspected and reprocessed according to defined reprocessing methods in the Instructions for Use.

The “IR” Telescopes are available with different directions of view to allow use for various applications in accordance with the intended use as submitted with this 510(k).

	Subject device WAIR100A, WAIR130A, WAIR500A, WAIR530A	Predicate device WA4KL100/WA4KL130 WA4KL500/WA4KL530
510(k) Number	K200542	K150633
Regulation number	21 CFR 876.1500 21 CFR 884.1720	21 CFR 876.1500 21 CFR 884.1720
Regulatory Class	II	II
Product code	GCJ / HET	GCJ / NMH / HET

	Subject device WAIR100A, WAIR130A, WAIR500A, WAIR530A	Predicate device WA4KL100/WA4KL130 WA4KL500/WA4KL530
Manufacturer	OLYMPUS WINTER & IBE GMBH	OLYMPUS WINTER & IBE GMBH
Laparoscope	rigid endoscope	rigid endoscope
Ocular coupling (y/n)	yes	yes
Integrated filters	IR filter	none
Lens coating	Near-infrared (NIR) optimized anti-reflective coating	Standard anti-reflective coating
Autoclavability	autoclavable	autoclavable
Reprocessing	manual and automated	manual and automated
Packaging	Cardboard box Non-sterile, re-usable	Cardboard box Non-sterile, re-usable

5.6 INDICATIONS FOR USE

VISERA ELITE II Infrared Imaging System

The VISERA ELITE II Infrared Imaging System is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. The VISERA ELITE II Infrared Imaging System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near-infrared imaging. Fluorescence imaging of biliary ducts with the VISERA ELITE II Infrared Imaging System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization

VISERA ELITE II XENON LIGHT SOURCE OLYMPUS CLV-S200-IR

The light source has been designed to be used with Olympus endoscopes, video system centers, light guide cables, and other ancillary equipment for endoscopic observation through visible and near-infrared fluorescence imaging with fluorescence agent.

TELESCOPE IR WAIR100A, WAIR130A
TELESCOPE ULTRA WAIR500A,WAIR530A

These endoscopes are intended to be used for endoscopy and endoscopic surgery within the thoracic and peritoneal cavities including the female reproductive organs. The device is also indicated for visualization of transanal and transvaginal natural orifice surgery. In combination with a compatible infrared imaging system, the telescope allows for fluorescence imaging.

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.

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

5.7 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

5.7.1 CLV-S200-IR

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

- Specified IR color modes

5.7.2 WAIR100A, WAIR130A, WAIR500A, WAIR530A

The WAIR100A, WAIR130A, WAIR500A, and WAIR530A have the same technological characteristics and design as the predicate device except for the following new features:

- An additional filter optimized for fluorescence imaging has been added within the ocular
- Coating of internal lenses for optimization of infrared imaging

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.

5.8 PERFORMANCE DATA

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

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing for the WAIR100A/130A/500A/530A was conducted and documentation is 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) Biocompatibility testing

Biocompatibility testing for the WAIR100A/130A/500A/530A 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". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test
- Systemic Toxicity Study in Mice
- Material mediated pyrogenicity

3) Software verification and validation testing

Software verification and validation testing for the OTV-S200 and CLV-S200-IR was conducted and documentation is 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".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted. 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.

5) Performance testing - Bench

Bench testing as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

[VISERA ELITE II Infrared Imaging System]

- Verification for photobiological safety of the illumination light

[WAIR100A/130A/500A/530A]
-DOV
-FOV
-MTF
-Distortion
-Ghost Image
-Internal reflections
-Spectral transmission of imaging system
-Expected Service Life
-Transport Drop
-Design Validation / Usability
-Illumination System performance Data
-Comparison of Optical Properties of Subject Device and predicate Device

6) Performance testing - Animal

The animal study using canines and swines was performed by taking videos that validate the performance of subject device in simulated body environment. The videos were evaluated by an independent Health Care Professional to demonstrate substantial equivalence in terms of IR observation.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk analysis

A Risk analysis for the CLV-S200-IR and WAIR100A/130A/500A/530A 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 have been applied to the CLV-S200-IR and WAIR100A/130A/500A/530A respectively;

CLV-S200-IR

- AAMI / ANSI ES 60601-1:2005 and A1:2012, C1:2009 and A2:2010
- IEC 60601-1-2:2014
- IEC 60601-2-18:2009
- ISO 14971:2007
- AAMI/ANSI/IEC 62304:2006

WAIR100A/130A/500A/530A

- AAMI / ANSI ES 60601-1:2005 and A1:2012, C1:2009 and A2:2010
- IEC 60601-2-18:2009
- IEC 60601-1-6:2013

- ISO 8600-1:2015
- ISO 8600-3:1997 + AM1(2003)
- ISO 8600-4:2014
- ISO 8600-5:2005
- ISO 8600-6:2005
- ISO 10993-1:2018
- AAMI/ANSI/ISO 10993-5:2009
- ISO 10993-12:2012
- ISO 14971:2007
- AAMI/ANSI/ISO 14937:2009
- ISO 17665:2006

5.9 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, CH-S200-XZ-EB, CLV-S200-IR and WAIR100A/130A/500A/530A raise no new issue of safety and effectiveness. They are substantially equivalent to the predicate devices in safety, efficacy, and performance.