DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 1, 2015

Olympus Medical Systems Corp.
Daphney Germain-Kolawole
Project Manager, Regulatory Affairs
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610

Re: K151011
Trade/Device Name: VISERA 4K UHD SYSTEM
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: Class II
Product Code: HET, EOB, EOQ, FGB, GCJ, NWB
Dated: August 31, 2015
Received: September 1, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151011

Device Name

VISERA 4K UHD SYSTEM

Indications for Use *(Describe)*

VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400
The camera control unit has been designed to be used with Olympus endoscopes, camera heads, light source, monitors, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

VISERA 4K UHD XENON LIGHT SOURCE OLYMPUS CLV-S400
The light source has been designed to be used with Olympus endoscopes, camera control unit, light guide cables, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
The camera head has been designed to be used with Olympus endoscopes, camera control unit, 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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510(k) SUMMARY
VISERA 4K UHD SYSTEM
ENDOSCOPIC IMAGING SYSTEM

October 1, 2015

I. General Information

■ Applicant:	Olympus Medical Systems Corp. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Establishment Registration No: 8010047
■ Official Correspondent:	Daphney Germain-Kolawole Project Manager, Regulatory Affairs Olympus Corporation of the Americas 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610, USA Phone: 484-896-5691 FAX: 484-896-7128
■ Manufacturer:	Shirakawa Olympus Co., Ltd. 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan Registration Number: 3002808148

II. Device Identification

■ Device Trade Name:	VISERA 4K UHD SYSTEM
■ Common Name:	ENDOSCOPIC IMAGING SYSTEM
■ Regulation Number:	884.1720 876.1500 874.4680
■ Regulation Name:	Gynecologic laparoscope and accessories Endoscope and Accessories Bronchoscope (flexible or rigid) and accessories
■ Regulatory Class:	II

- Classification Panel: General and plastic surgery,
  Obstetrics/Gynecology
  Ear Nose & Throat

- Product Code: HET; Laparoscope, Gynecologic (And Accessories)
  EOB; Nasopharyngoscope (Flexible Or Rigid)
  EOQ; Bronchoscope (Flexible Or Rigid)
  FGB; Ureteroscope And Accessories, Flexible/Rigid
  GCJ; Laparoscope, General & Plastic Surgery
  NWB; Endoscope, Accessories, Narrow Band Spectrum

III. Predicate Device Information

Subject Device (Part of this submission)	**Predicate Device**	**Predicate Device 510(k) No.**
VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400	VISERA ELITE VIDEO SYSTEM CENTER OLYMPUS OTV-S190	K111425
VISERA 4K UHD XENON LIGHT SOURCE OLYMPUS CLV-S400	VISERA ELITE XENON LIGHT SOURCE OLYMPUS CLV-S190	K111425
4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB	AUTOCLAVABLE CAMERA HEAD OTV-Y0017	K102059

IV. Device Description

The VISERA 4K Ultra-High Definition (UHD) SYSTEM has been designed to be used with Olympus camera heads, endoscopes, camera control unit, light source, monitors, light guide cables and other ancillary equipment for endoscopic diagnosis, treatment and observation. The VISERA 4K UHD SYSTEM consists of a camera control unit (CCU), light source, camera head, endoscope, monitors, printer, medical image storage device, cables and workstation.

The primary components of the subject system, which are part of this submission, are:

- VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400
- VISERA 4K UHD XENON LIGHT SOURCE OLYMPUS CLV-S400
- 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB

The VISERA 4K UHD SYSTEM receives optical image from a variety of endoscopes that are attached to the camera head via coupler and use image sensor to convert optical image into electronic signal. The CCU acts as the the control center of the system. The light source supplies light.

The VISERA 4K UHD SYSTEM can provide high quality 4K images. The VISERA 4K UHD SYSTEM supports wider color gamut. The new 4K camera heads incorporate a complementary metal oxide semiconductor (CMOS) image sensor. A camera control unit introduces a touch panel graphical interface.

V. Indications for Use

VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400
The camera control unit has been designed to be used with Olympus endoscopes, camera heads, light source, monitors, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

VISERA 4K UHD XENON LIGHT SOURCE OLYMPUS CLV-S400
The light source has been designed to be used with Olympus endoscopes, camera control unit, light guide cables, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
The camera head has been designed to be used with Olympus endoscopes, camera control unit, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

VI. Comparison of Technological Characteristics

The VISERA 4K UHD SYSTEM has the same technological characteristics and design as the predicate device except the following new features:

- The VISERA 4K UHD SYSTEM can provide high quality 4K images
- The VISERA 4K UHD SYSTEM supports wider color gamut
- New 4K camera head incorporate a CMOS image sensor
- The CCU introduces touch panel graphical interface

As shown in the comparison tables at the end of this section, all other technological characteristics of both subject and predicate deveices are identical.

VII. Summary of non-clinical testing

The differences of technological characteristics between the predicate device and the subject device are confirmed that they are substantially equivalent through the following tests and standards.

- A performance testings were conducted to demonstrate that the VISERA 4K UHD SYSTEM performs according to specifications and functions as intended. Tests results obtained verified the safety and effectiveness of the devices in accordance with design specifications and applicable standards..

- The instructions for reprocessing of the subject devices include Cleaning, Disinfection, and Sterilization. All cleaning, disinfection, and sterilization methods have been validated.

- The software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

- Electromagnetic compatibility, electric safety, and thermal safety had been confirmed.

- Risk analysis was carried out 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 VISERA 4K UHD System;

- IEC 60601-1: 2005+A1,
- IEC 60601-1-2: 2007,
- IEC 60601-2-18: 2009,
- IEC 60825-1: 2007,
- ISO 14971: 2007.

VIII. Conclusion

The VISERA 4K UHD SYSTEM has the same intended use and similar indications for use, technological characteristics, and principal operations. The technological differences raised no new issues of safety or effectiveness as compared to its predicate device. Performance tests demonstrate that the VISERA 4K UHD SYSTEM performs according to specifications and functions as intended. Therefore, the VISERA 4K UHD SYSTEM is substantially equivalent to its predicate device.

Device Comparison Tables

Table1 :Comparison table of the OTV-S400

		Subject device: OTV-S400 **VISERA 4K UHD CAMERA CONTROL UNIT**	**Predicate device: OTV-S190** **VISERA ELITE VIDEO SYSTEM CENTER**
510(k)		K151011	K111425
Regulation number		Same	884.1720, 874.4680, 876.1500
Device class		Same	II
Product code		Same	HET, EOB, EOQ, FGB, GCJ, NWB
Indications for use		The camera control unit has been designed to be used with Olympus endoscopes, camera heads, light source, monitors and other ancillary equipment for endoscopic diagnosis, treatment, and 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.
Power Supply		Same	100-240V~ ±10% 50/60Hz±1Hz
Dimension		390(W) × 160(H) × 506(D) mm	375(W) × 91(H) × 489(D) mm
Weight		13.5Kg	8.8Kg
Input power		３５０VA	150VA
Image observation	**Resolution**	4K（4096pxl×2160pxl）	SD/HD（1920pxl×1080pxl）
	Image signal output	SDI（3G/HD）	RGB：2, Y/C：2, VBS：2, SDI：2, DVI：1
	Iris mode selection	AUTO/CENTER	AUTO/PEAK/AVE
	Standard Color Chart Output	Same	Color bar image
	Color Tone Adjustment	Same	R,B,C:±8 steps
	Observation light imaging	Same	WLI (white light imaging) NBI (narrow band imaging)
Operating Environme	**Ambient temperature**	10 – 35℃(50 – 95°F)	10 to 40℃
	Humidity	Same	30～85% RH
	Atmosphere	Same	700～1060 hPa
Electric safety		Comply to IEC 60601-1: 2005+A1, IEC 60601-2-18: 2009	Comply to IEC 60601-1: 1998+A1,A2, IEC 60601-2-18: 1996+A1
Type of Protection against Electric Shock		Same	Class Ⅰ
Laser Product		Comply to IEC 60825-1: 2007	N/A
Degree of Protection against Electric Shock of Applied Part		Type BF applied part	Type BF or CF applied part (Depends on applied part)
EMC		Same	Comply to IEC 60601-1-2: 2007

Table2:Comparison table of the CLV-S400

	Subject device: CLV-S400 **VISERA 4K UHD XENON LIGHT SOURCE**	**Predicate device: CLV-S190** **VISERA ELITE XENON LIGHT SOURCE**
510(k)	K151011	K111425
Regulation number	Same	884.1720, 874.4680, 876.1500
Device class	Same	II
Product code	Same	HET, EOB, EOQ, FGB, GCJ, NWB
Indications for use	The light source has been designed to be used with Olympus endoscopes, camera control unit, light guide cables, and other ancillary equipment for endoscopic diagnosis, treatment and 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.
Power Supply	Same	100-240 V~ ±10% 50/60 Hz±1Hz
Dimension	390 (W) ×162 (H)×551 (D) mm	383 (W) × 162 (H) × 53 6(D) mm
Weight	15.5kg	14.9kg
Input power (Consumption Electric Power)	500 VA	500 VA
Examination Lamp	Same	Xenon short-arc lamp (ozone-free) 300W
Average Lamp Life	Same	Approximately 500 hours of continuous use
Emergency Lamp	Same	Halogen Lamp 12V 35W
Average Emergency Lamp Life	Same	Approximately 500 hours
Automatic Exposure	Same	17 steps
Electric safety	Comply to IEC 60601-1: 2005+A1, IEC 60601-2-18: 2009	Comply to IEC 60601-1: 1998+A1,A2, IEC 60601-2-18: 1996+A1
Type of Protection against Electric Shock	Same	Class I
Degree of Protection against Electric Shock of Applied Part	Type BF applied part	Type BF or CF applied part (Depends on applied part)
EMC	Same	Comply to IEC 60601-1-2: 2007

Table3 :Comparison table of the CH-S400-XZ-EB

		Subject device: CH-S400-XZ-EB 4K CAMERA HEAD	**Predicate device: OTV-Y0017 AUTOCLAVABLE CAMERA HEAD**
510(k)		K151011	K102059
Regulation number		Same	876.1500
Device class		Same	II
Product code		Same	FET, NWB
Indications for use		The camera head has been designed to be used with Olympus endoscopes, camera control unit, 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.
Dimension	**Camera Head**	W43.6 mm × H49.5 mm × L122.5 mm	38 mm×106 mm
	Cable	5.1 mm × 3 m	6.8 mm×4 m
	Weight	280 g (excluding cable)	215 g （excluding cable）
Operating Environme	**Ambient temperature**	10 – 35℃(50 – 95°F）	10 to 40℃
	Humidity	Same	30～85% RH
	Atmosphere	Same	700～1060 hPa
Reprocessing		End user sterilized EOG/ STERRAD	End user sterilized AUTOCLAVE
Electric safety		Comply to IEC 60601-2-18: 2009	Comply to IEC 60601-2-18: 1996+A1
Laser Product		Comply to IEC 60825-1: 2007	N/A
EMC		Comply to IEC 60601-1-2: 2007	Comply to IEC 60601-1-2: 2001+A1