October 17, 2017

Olympus Medical Systems Corp.
% Sheri L. Musgnung
Regulatory Affairs Manager
Olympus Corporation of the Americas
3500 Corporate Parkway P.O. Box 610
Center Valley, PA 18034-0610

Re: K172817
Trade/Device Name: 1) 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
2) 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FET, NWB
Dated: September 15, 2017
Received: September 18, 2017

Dear Sheri L. Musgnung:

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 (DICE) 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 (DICE) 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,

Charles Viviano -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)*
K172817

Device Name
1) 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
2) 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA

Indications for Use *(Describe)*
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
&
4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA

September 15, 2017

I. General Information

- Applicant: Olympus Medical Systems Corp.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
  Establishment Registration No: 8010047

- Official Correspondent: Sheri L. Musgnung,
  Regulatory Affairs Manager
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3147
  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: 1) 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
  2) 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA
- Common Name: Camera Heads
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology

- Product Code: FET: Endoscopic video imaging system/component, gastroenterology-urology
  NWB: Endoscope, Accessories, Narrow Band Spectrum

III. Predicate Device Information

Predicate Device	Predicate Device 510(k) No.
4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB **(as cleared via VISERA 4K UHD System)**	K151011 (VISERA 4K UHD SYSTEM)

IV. Device Description

Olympus intends to introduce two new models of 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB and 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA to mainly add sterilization methods to the predicate device 4K CAMERA HEAD which has been cleared as part of VISERA 4K UHD System (K151011).

Both 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB and 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA are structurally consisted of endoscopic coupler end, camera cable and video connector end.

The 4K Camera Heads function as receiving optical image from a variety of endoscopes that are attached to it via coupler and using incorporated complementary metal oxide semiconductor (CMOS) image sensor to convert optical image into electronic signal. The signal is subsequently transformed into laser by laser diodes and input to VISERA 4K UHD CAMERA CONTROL UNIT by optical fiber for further processing with other ancillary equipment on endoscopic diagnosis, treatment, and observation.

V. Indications for Use

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.

4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA
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 subject devices, 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB and 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA, have the same fundamental scientific technology; indications for use; principal of operation; and energy source as the legally marketed 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB cleared via the VISERA 4K UHD SYSTEM in K151011. The modifications between subject devices and predicate device are indicated as follows:

1) Addition of sterilization methods for reprocessing the device by user
2) Minor changes on material, dimension, appearance, weight specification

VII. Summary of non-clinical testing

The design verification tests were conducted and validated to be in accordance with ISO 14971:2007, and the design control procedure complies with requirements as specified in 21 CFR 820.30.

VIII. Conclusion

4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB and 4K AUTOCLAVABLE CAMERA HEAD OLYMPUS CH-S400-XZ-EA have the same indications for use; fundamental scientific technology; principal of operation; and energy source. The addition of sterilization methods as well as the other minor modifications have been validated and raised no new issues of safety or effectiveness as compared to the predicate device. Therefore, both of the subject devices are considered to be substantially equivalent to their predicate 4K CAMERA HEAD in VISERA 4K UHD system.