December 5, 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: K172618
Trade/Device Name: SYSTEMS INTEGRATION ENDOALPHA MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4 Software Version 1
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ, ODA
Dated: November 1, 2017
Received: November 2, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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)*
K172618

Device Name
SYSTEMS INTEGRATION ENDOALPHA MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4 Software Version 1

Indications for Use *(Describe)*
This medical control unit for endosurgery has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

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.

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510(k) SUMMARY

SYSTEMS INTEGRATION ENDOALPHA
MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4
Software Version 1

August 30, 2017

I. General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 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: 484-896-3147Fax: 484-896-7128 Email: sheri.musgnung@olympus.com
■ Manufacturer:	SHIRAKAWA OLYMPUS CO., LTD. 3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima, 961-8061, Japan Establishment Registration Number: 3002808148

II. Device Identification

■ Device Trade Name:	SYSTEMS INTEGRATION ENDOALPHA MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4 Software Version 1
■ Common Name:	Endosurgery system
■ Regulation Number:	876.1500
■ Regulation Name:	Endoscope and accessories
■ Regulatory Class:	II
■ Classification Panel:	Gastroenterology and urology

- Product Code: GCJ and ODA

III. Predicate Device Information

- Device Name: SYSTEMS INTEGRATION ENDOALPHA MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-3 Software Version 4
- Common Name: Endosurgery system
- Regulation Number: 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
- 510(k) Number: K121701

IV. Device Description

The SYSTEMS INTEGRATION ENDOALPHA MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4 Software Version 1 (hereinafter referred to as “UCES-4”) has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

- System Components

The UCES-4 consists of the following components.

Model	Device description
UCES-4	MEDICAL CONTROL UNIT FOR ENDOSURGERY
MAJ-2191	EXTENSION UNIT FOR UCES-4
MAJ-2249	INTERFACE FOR ESU (VIO SERIES)
MAJ-2250	INTERFACE FOR ESU (FORCE SERIES)
MAJ-2251	UNIVERSAL INTERFACE
MAJ-2268	INTERFACE FOR OLYMPUS LINK DEVICE

- Structure

The UCES-4 has built-in power supply circuit, main control circuit, communication control circuit, and data storage device. Through communications with each of the

ancillary equipment, it provides central display of the ancillary equipment status and performs centralized operation of the ancillary equipment via the touch panel.

■ Principle

Communicating with the connected ancillary equipment, the UCES-4 displays the information of the communications on the touch panel. It sends input commands from input devices such as the touch panel to the ancillary equipment to perform centralized control.

V. Indications for Use

This medical control unit for endosurgery has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

VI. Comparison of Technological Characteristics

The UCES-4 has the same technological characteristics as the predicate device as follows:

- Operating principle
- Electrical characteristic
- Mechanical characteristic
- Communication characteristic
- Energy source
- Material (no patient contacting material)

The UCES-4 has modified the software and hardware, and the following technological characteristics are different from the predicate device.

- Performance
- Graphical user interface
- Compatibility with other devices

The validation testing demonstrated that these differences do not affect the safety and effectiveness of the subject device.

VII. Summary of Non-Clinical Testing

Non-clinical testing was not conducted since the basic technological characteristics of the subject device are identical to the predicate device.

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.

- 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".
- The electromagnetic compatibility and electric safety had been confirmed.
- The risk management was performed in accordance with established in-house acceptance criteria based on ISO 14971:2007.
- The human factors activities were performed in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices".

The following voluntary standards have been applied to the UCES-4;

- IEC 60601-1: 2005+A1
- IEC 60601-1-2: 2014
- IEC 60601-2-18: 2009
- ISO 14971: 2007

VIII. Conclusion

Compared to the legally marketed predicate device, the UCES-4 does not incorporate any significant changes in the indications for use, method of operation, material, or design that could affect the safety or effectiveness of the subject device.