

K102763
FEB 15 2011

510(k) SUMMARY

SYSTEMS INTEGRATION ENDOALPHA

December 7, 2010

1 General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507
Establishment Registration No: 8010047

- Official Correspondent:
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Establishment Registration No: 2429304

- Manufacturer: SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun
Fukushima, JAPAN 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Name: SYSTEMS INTEGRATION ENDOALPHA
(MEDICAL CONTROL UNIT FOR ENDOSURGERY
UCES-3) Software Version 2

- Common Name: Endosurgery system
- Regulation No: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Product Code: ODA, KOG, and GCJ
- Classification Panel: Gastroenterology/Urology
- Prescription Status: Prescription device
- Performance Standards: None established under Section 514.

3 Predicate Device Information

- Device Name: SYSTEMS INTEGRATION ENDOALPHA
- 510(k) No: K100345
- Decision Date: 03/22/2010

4 Device Description

The Systems Integration ENDOALPHA 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.

The ENDOALPHA integrated electrosurgical system has the following system functions.

1) Centralized control from a non-sterilized area

The ancillary equipment connected to the MEDICAL CONTROL UNIT FOR ENDOSURGERY (UCES-3) and EXTENSION UNIT FOR UCES-3 (MAJ-1827) can be controlled in a centralized way using the TOUCH PANEL FOR ENDOALPHA (MAJ-1828).

2) Centralized control from a sterilized area

- Ancillary equipment can be controlled by means of voice from a sterilized area.
- Ancillary equipment can be controlled utilizing remote switches of the endoscope connected to the VIDEOSYSTEM CENTER (OLYMPUS CV-180, OLYMPUS OTV-S7Pro) in a sterilized area.

3) Centralized display

The settings of the functions of connected ancillary equipment can be displayed on the screen of the TOUCH PANEL FOR ENDOALPHA (MAJ-1828) and UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176).

4) Message display

Various warning and error messages can be displayed on the screen of the TOUCH PANEL FOR ENDOALPHA (MAJ-1828) and UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176).

5) Voice reply

The ancillary equipment settings, warning messages, error messages can be fed back in voice.

6) Automatic settings

The default settings of all ancillary equipment can be registered on a per-procedure basis and recalled with a one-touch operation for setting the ancillary equipment to the required settings at once.

7) Scene settings

The operations of the ancillary equipment, performed at the beginning of each scene in the procedure, can be registered and recalled with a one-touch operation for performing them at once.

8) Display customization

The contents of the display of the TOUCH PANEL FOR ENDOALPHA (MAJ-1828) and UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176) can be customized.

9) Still image viewing

Still images recorded in a USB thumb drive (SDCZ8) can be viewed on the UNIVERSAL DISPLAY FOR ENDOALPHA (MAJ-1176).

10) Automatic smoke evacuation

When a recommended electrosurgical unit and/or SonoSurg Generator (SonoSurg-G2) and an insufflator are connected to the MEDICAL CONTROL UNIT FOR ENDOSURGERY (UCES-3) or EXTENSION UNIT FOR UCES-3 (MAJ-1827), the generated smoke or vapor can be evacuated automatically.

The modifications made to the subject device are as follows:

- A) Additional medical devices are added to list of recommended ancillary equipment
- B) Improved interfacing between UCES-3 and the Advanced System
- C) Increase in the maximum number of connectable surgical lights
- D) Reduction in the startup time for the UCES-3
- E) An additional language setting for text indications
- F) Addition of the UPGRADE KIT FOR UCES-3 (Version 2) MAJ-1943

5 Intended Use

SYSTEMS INTEGRATION ENDOALPHA

(MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-3) Software Version 2

The Systems Integration ENDOALPHA 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.

UPGRADE KIT FOR UCES-3 (Version 2) MAJ-1943

This equipment has been designed to install software on the ENDOALPHA UCES-3, MAJ-1831, MAJ-1832, MAJ-1834, and MAJ-1862.

The intended use of the SYSTEMS INTEGRATION ENDOALPHA (MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-3) Software Version 2 as stated above is to enable a central system to control various pieces of ancillary equipment. However, the previously cleared indications for use for each separate ancillary device dictate the type of procedures that may be performed. This information is included in the instruction manual for each ancillary piece of equipment.

The Intended Use of the SYSTEMS INTEGRATION ENDOALPHA (MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-3) Software Version 2 is identical to the Intended Use previously cleared for the SYSTEMS INTEGRATION ENDOALPHA, K100345.

6 Comparison of technological characteristics with the predicate device

The modified SYSTEMS INTEGRATION ENDOALPHA has the same hardware as the predicate device and only software has been modified. Therefore, the modified SYSTEMS INTEGRATION ENDOALPHA has the same technological characteristics as the predicate device as follows:

- Operating principle
- Dimensional specifications
- Electrical characteristics
- Mechanical characteristics
- Communication characteristics

- Energy source
- Material (no patient contacting material)

The software modifications are minor and substantially equivalent to the predicate device. Therefore, the modified SYSTEMS INTEGRATION ENDOALPHA has the similar technological characteristics as the predicate device as follows:

- Performance
- Graphical user interface
- Compatibility with other devices as listed in the product labeling

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment. A list of the testing included in the design verifications tests is as follows:

- Operation/verification testing for the improved interfacing between UCES-3 and the Advanced System
- Operation/verification testing for the new compatible ancillary equipment
- Operation/verification testing for the increase in the maximum number of connectable surgical lights
- Performance testing for the startup time of the UCES-3
- Operation testing for additional language setting for text indications

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." A list of the testing included in the software validation activities is as follows:

- Unit level testing (Module verification)
- Integration level testing (Task verification)
- System level testing (System verification)
- Simulated use testing (Validation)

8 Conclusion

The modified SYSTEMS INTEGRATION ENDOALPHA has the following similarities to the predicate device:

- Has the same intended use,
- Uses the same operating principle

In summary, the modified SYSTEMS INTEGRATION ENDOALPHA described in this submission is, in our opinion, substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Olympus Medical Systems Corp.
c/o Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs Project Manager
Olympus America Inc.
3500 Corporate Parkway
CENTER VALLEY PA 18034

FEB 15 2011

Re: K102763
Trade/Device Name: Systems Integration Endoalpha (Medical Control Unit
for Endosurgery UCES-3) Software Version 2
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODA and GCJ
Dated: January 13, 2011
Received: January 18, 2011

Dear Ms. Kluesner:

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.

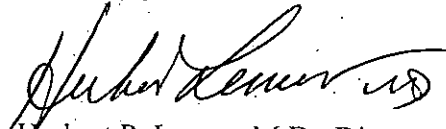
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

Indications for Use

510(k) Number (if known): K102763

Device Name: SYSTEMS INTEGRATION ENDOALPHA

(MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-3)

Software Version 2

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SYSTEMS INTEGRATION ENDOALPHA

(MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-3) Software Version 2

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Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K102763

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number _____

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