October 10, 2019

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

Re: K190772
Trade/Device Name: SURGICAL MICROSCOPE SYSTEM ORBEYE with IR
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI, EPT
Dated: September 10, 2019
Received: September 11, 2019

Dear Sheri 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. 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
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/combo-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.


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,

Matthew C. Krueger -S

Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
  Neurointerventional
  and Neurodiagnostic Devices
OHT5: Office of Neurological
  and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

This instrument has been designed to be used for viewing intra-operative blood flow in the cerebral vascular area and is intended for use in adults only.

Type of Use (Select one or both, as applicable)

[X] 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
PRASStaff@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."
Indications for Use

510(k) Number (if known)
K190772

Device Name
INFRARED FILTER UNIT MAJ-2307

Indications for Use (Describe)
This instrument has been designed to be used for viewing intra-operative blood flow in the cerebral vascular area and is intended for use in adults only.

Type of Use (Select one or both, as applicable)

[X] 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

5.1 GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507

■ Contact Person: Sheri L. Musgnung
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Phone: 484-896-3147
Fax: 484-896-7128
Email: sheri.musgnung@olympus.com

■ Manufacturing Site
Olympus Medical Systems Corp.
Hinode Plant
34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo 190-0182, Japan

5.2 DEVICE IDENTIFICATION

■ Device Name
SURGICAL MICROSCOPE SYSTEM ORBEYE with IR

■ Model Name
[System components]
ORB EYE SURGICAL MICROSCOPE  OME-V200
LED LIGHT SOURCE   OME-L200
INFRARED IMAGING UNIT  MAJ-2304
INFRARED FILTER UNIT  MAJ-2307
AUTO FOCUS UNIT  MAJ-2303
FOOT SWITCH  MAJ-2301
4K COMBINED CABLE 10M  MAJ-2309
RECOR DER REMOTE CABLE 3P  MAJ-2310
POWER CORD US  MAJ-2312
Indocyanine Green for Injection, USP

■ Common Name
Surgical microscope system

■ Regulation Number
892.1600
5.3 PREDICATE DEVICE

**Predicate device**

<table>
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<tr>
<th>Device name</th>
<th>510(k) Submitter</th>
<th>510(k) No.</th>
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<tbody>
<tr>
<td>Leica FL800</td>
<td>LEICA BIOSYSTEMS RICHMOND, Inc</td>
<td>K141136</td>
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**Reference device**

<table>
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<th>Device name</th>
<th>510(k) Submitter</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
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<td>1</td>
<td>SPY SCOPE INTRA-OPERATIVE OPERATING SYSTEM</td>
<td>NOVADAQ TECHNOLOGIES, INC.</td>
<td>K091515</td>
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<tr>
<td>2</td>
<td>SURGICAL MICROSCOPE SYSTEM ORBEYE</td>
<td>OLYMPUS MEDICAL SYSTEMS CORP.</td>
<td>510(k) exempt</td>
</tr>
</tbody>
</table>

510(k) exempt (under 878.4700 EPT)

5.4 DEVICE DESCRIPTION

The SURGICAL MICROSCOPE SYSTEM ORBEYE with IR is used for viewing intra-operative blood flow in the cerebral vascular area.

When the INFRARED IMAGING UNIT MAJ-2304 and the INFRARED FILTER UNIT MAJ-2307 are mounted on the LED LIGHT SOURCE OME-L200 and the ORBEYE SURGICAL MICROSCOPE OME-V200 respectively, it allows the surgical microscope to produce excitation light and resolve fluorescence light from the fluorescent ICG. The subject device of this 510(k) submission, ORBEYE with IR system, enables the microscopic observation with IR (Infrared) Imaging.
The ORBEYE with IR system will be marketed as a System and will also be sold as individual components.

The subject system consists of the following primary components:

- ORBEYE SURGICAL MICROSCOPE OME-V200
- LED LIGHT SOURCE OME-L200
- INFRARED IMAGING UNIT MAJ-2304
- INFRARED FILTER UNIT MAJ-2307
- AUTO FOCUS UNIT MAJ-2303
- FOOT SWITCH MAJ-2301
- 4K COMBINED CABLE 10M MAJ-2309
- RECORDER REMOTE CABLE 3P MAJ-2310
- POWER CORD US MAJ-2312
- Indocyanine Green for Injection, USP

**ORBYE SURGICAL MICROSCOPE OME-V200**
OME-V200 is a surgical microscope to enlarge the images of the surgical site or enable stereoscopic observation. In the microscope unit, two image sensors in UHD (ultra high definition) resolution are incorporated. Connecting the microscope with an UHD-3D monitor enables displaying enlarged images or viewing stereoscopic images in UHD resolution.

**LED LIGHT SOURCE OME-L200**
OME-L200 is an LED light source to supply illumination light to the surgical site through the OME-V200.

**INFRARED IMAGING UNIT MAJ-2304**
MAJ-2304 is a unit that enables IR Imaging.

**INFRARED FILTER UNIT MAJ-2307**
MAJ-2307 is a unit that switches filters to enable IR Imaging.

**AUTO FOCUS UNIT MAJ-2303**
MAJ-2303 is a unit that enables Auto Focus.

**FOOT SWITCH MAJ-2301**
MAJ-2301 is a foot switch and receiver that operates a surgical microscope.

**4K COMBINED CABLE 10M MAJ-2309**
MAJ-2309 is a video cable for displaying 4K video of a surgical microscope on a monitor.

**RECORDER REMOTE CABLE 3P MAJ-2310**
MAJ-2310 is a cable for operating the recorder from a surgical microscope.
POWER CORD US MAJ-2312
MAJ-2312 is the power cable for supplying power to the surgical microscope.

Indocyanine Green for Injection, USP
Fluorescent agent for IR imaging, supplied from Diagnostic Green LLC.

5.5 INDICATIONS FOR USE

SURGICAL MICROSCOPE SYSTEM ORBEYE with IR
This instrument has been designed to be used for viewing intra-operative blood flow in the cerebral vascular area and is intended for use in adults only.

INFRARED FILTER UNIT MAJ-2307
This instrument has been designed to be used for viewing intra-operative blood flow in the cerebral vascular area and is intended for use in adults only.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The SURGICAL MICROSCOPE SYSTEM ORBEYE with IR has the same technological characteristics and design as the predicate device except for the following new features:

1. Image sensor
2. Software
3. Excitation light
4. UHD (Ultra High Definition) technology

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.

5.7 PERFORMANCE DATA
The following performance data were provided in support of the substantial equivalence determination.

1) **Software verification and validation testing**
   Software verification and validation testing for the SURGICAL MICROSCOPE SYSTEM ORBEYE with IR were conducted and documentation was 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”.

2) **Electrical safety and electromagnetic compatibility (EMC)**
   Electrical safety and EMC testing were conducted on the SURGICAL MICROSCOPE SYSTEM ORBEYE with IR. The system complies with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

3) **Performance testing - Bench**
   Bench testing for the SURGICAL MICROSCOPE SYSTEM ORBEYE with IR as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.
   - Verification for the IR illumination light wavelength
   - Verification for the optical property of the objective IR optical systems
   - Verification for patient safety of the IR illumination light (focusing on patient’s thermal injury)
   - Verification for patient safety of the IR illumination light (focusing on users’ eye injury)
   - Verification for the wireless connection mechanism not to be interfered by the radio waves from other equipment

4) **Performance testing - Animal**
   In the animal study, indocyanine green (ICG) solution was intravenously administered to 5 male beagle dogs of 7-8 months old. The cerebral tissue, the cerebral surface arteries and veins were observed under near-infrared light (IR) using the subject device system and Leica M525 F50 in combination with the predicate device. The animal testing is performed in accordance to 21 CFR Part 58 - GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES.

   Neither the subject system nor predicate system induced any gross pathological abnormalities in the observation.
5) Performance testing - Clinical
   No clinical study was performed to demonstrate substantial equivalence.

6) Risk analysis
   Risk analysis for the SURGICAL MICROSCOPE SYSTEM ORBEYE with IR 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.

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the SURGICAL MICROSCOPE SYSTEM ORBEYE with IR raises no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, efficacy and performance.