March 13, 2018

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

Re: K173459
Trade/Device Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM
Regulation Number: 21 CFR§ 876.1300
Regulation Name: Ingestible Telemetric Gastrointestinal Capsule Imaging System
Regulatory Class: II
Product Code: NEZ
Dated: January 31, 2018
Received: February 1, 2018

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173459

Device Name
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

Indications for Use *(Describe)*
The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is intended for visualization of the small intestine mucosa.
- It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia(IDA) not detected by upper and lower endoscopy.

The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM may be used as a tool in the detection of abnormalities of the small intestine and is intended for use in adults only.

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.

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"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."

March 6, 2018

5. 510(k) SUMMARY

5.1 General Information

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

- Contact Position: Daphney Germain-Kolawole
  Senior 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
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5.2 Device Identification

- Device Trade Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM
- Common Name: Capsule Imaging System
- Regulation Number: 876.1300
- Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
- Regulatory Class: II (Special Controls)
- Classification Panel: Gastroenterology and urology
- Product Code: NEZ

5.3 Predicate Device Information

Primary Predicate Device (PD1)		
Model name	Applicant	510(k) No.
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM	OLYMPUS MEDICAL SYSTEMS CORP.	K163069
Additional Predicate Device (PD2)		
Model name	Applicant	510(k) No.
OLYMPUS CAPSULE ENDOSCOPE SYSTEM	OLYMPUS MEDICAL SYSTEMS CORP.	K090210

5.4 Device Description

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is a capsule imaging system used for visualization of the small intestine mucosa.
This system consists of capsule endoscopes which capture images and transmit the data, an antenna unit and a recorder which are secured around the patient and receive data from the capsule, and workstation software which downloads the image data from the recorder and processes images for visualization. After the visualization, the diagnostic review (also known as reading) of images would start with user selectable OMNI mode feature. OMNI mode is an algorithm that assists the physician in reviewing the Capsule Endoscopy(CE) case data. The components of this SYSTEM are listed below.(Table 5-1)

Table 5-1: ENDOCAPSULE SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

Trade or Proprietary or Model Name for The Subject Device		Model Number
ENDOCAPSULE SMALL INTESTINAL CAPSULE ENDOSCOPE SET		MAJ-2027
(Components)	CAPSULE ENDOSCOPE (5 pcs.)	EC-S10
ENDOCAPSULE RECORDER SET		MAJ-2029
(Components)	CAPSULE ACTIVATOR (2 pcs.)	MAJ-1478
	ENDOCAPSULE RECORDER	OLYMPUS RE-10
	BATTERY PACK	MAJ-2030
	ANTENNA UNIT	MAJ-2031
	CRADLE	MAJ-2032
	RECORDER HOLDER	MAJ-2033
	ANTENNA HOLDER	MAJ-2034
LEAD ANTENNAUNIT		MAJ-2294
ANTENNA LEAD COVER		MAJ-1470
ENDOCAPSULE SOFTWARE 10		MAJ-2188
ENDOCAPSULE SOFTWARE 10 LIGHT		MAJ-2189
ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE		MAJ-2190

5.5 Indications for Use

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM is intended for visualization of the small
intestine mucosa.

- It may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- It may be used in the visualization and monitoring of lesions that may be potential causes of iron deficiency anemia(IDA) not detected by upper and lower endoscopy.

The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM may be used as a tool in the detection of abnormalities of the small intestine and is intended for use in adults only.

5.6 Comparison of Technological Characteristics

The OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM has the same technological characteristics and design as the predicate device except for Addition of Lead Type Antenna.

All other technological characteristics of both the subject and primary predicate devices are identical.

5.7 Performance Data

5.7.1 Summary of Non-Clinical Testing

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

-Performance testing - Bench

Performance testing was conducted to demonstrate that the OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM performs according to specifications and functions as intended. Test results verified the safety and effectiveness of the devices in accordance with design specifications and applicable standards. Conducted performance testings are listed below.

- Software verification and validation testing
- Electrical safety and electromagnetic compatibility (EMC) test
- Performance testing of radio signal communication
- Radio Interference testing
- FCC Test

-Risk Management

Risk management 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.

5.7.2 Summary of Clinical Testing

The clinical testing was performed to support the claims for improvement of capsule reading efficiency and the reduction of redundant images. A multicenter, randomized trial was conducted to examine the hypothesis that OMNI mode can remove and store redundant images of the same region of the small bowel and is superior to conventional review of all CE images (Normal mode) in terms of the time required to review the case data. Seven different expert CE physicians, blinded to the reading mode, reviewed the cases in randomized order . The review time was compared between Normal mode and OMNI mode. OMNI mode required, on average, 27.3 minutes for review while Normal mode required 75.1 minutes, on average ($p<0.001$), which is a 64% reduction. The result supports the claims for improvement of capsule reading efficiency and the reduction of redundant images. The conducted performance testing is shown below.

- Evaluation of performance of the Omni mode for detecting video capsule endoscopy images:A multicenter randomized controlled trial

5.8 Conclusion

Compared to the primary predicate device, the OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM 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. Therefore, the subject device is substantially equivalent to the cited primary predicate device.