January 19, 2017

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

Re: K163069
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: November 1, 2016
Received: November 2, 2016

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.

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 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 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,

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
Device Name
OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

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.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

January 18, 2017

I. General Information

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

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961-8061, Japan
Establishment Registration Number: 3002808148

OLYMPUS MEDICAL SYSTEMS CORP.
HINODE PLANT
34-3 Hirai, Hinode-machi, Nishitama-Gun, Tokyo,
190-0182, Japan
Establishment Registration Number: 3003637092

II. Device Identification

■ Device Trade Name: OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM

■ Common Name: Capsule Imaging System

■ Regulation Number: 876.1300
III. Predicate Device Information

<table>
<thead>
<tr>
<th>Model name</th>
<th>Applicant</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OLYMPUS CAPSULE ENDOSCOPE SYSTEM (ENDOCAPSULE SOFTWARE 10, ENDOCAPSULE SOFTWARE 10 LIGHT)</td>
<td>OLYMPUS MEDICAL SYSTEMS CORP.</td>
<td>K142680</td>
</tr>
</tbody>
</table>

IV. Device Description

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. The devices comprising this system, device design, and specifications are identical with the legally marketed predicate device, K142680, with the exception of minor modifications that did not trigger the need for a new 510(k) and were documented internally at Olympus.

- The ENDOCAPSULE SMALL INTESTINAL CAPSULE ENDOSCOPE (OLYMPUS EC-10) is operated by mercury-free silver oxide batteries while the batteries for the predicate device contain mercury.
- The ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE (MAJ-2190) is an upgraded software version to the previous models listed below:
  - ENDOCAPSULE SOFTWARE 10 SERVER-CLIENT (Ver.1.00 and Ver.1.01)
  - ENDOCAPSULE SOFTWARE 10 CLIENT (Ver.1.00 and Ver.1.01)

Expanding the indications for use to include the detection of Crohn’s disease, obscure bleeding, and iron deficiency anemia (IDA) for this system is the scope of this submission.
V. 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.

VI. Comparison of Technological Characteristics

Compared to the legally marketed predicate device, technological characteristics of the subject device are identical to the predicate device.

VII. Summary of Non-Clinical Testing

[Change in batteries]
To validate the change to mercury-free silver oxide batteries, the following tests were conducted.

• Battery Life
• Test on Temperature and Humidity in Medical Environment
• Test on Temperature and Humidity During Transportation and Storage

[Software upgrade]
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 device software is considered a Moderate Level of Concern.

The validation tests were performed against each function in regards to the following points.

• Detail information on functional requirements
• Performance requirements
• Security requirements
• Usability engineering requirements
• Database requirements
• Operation and maintenance requirements

The purpose of this submission is to expand the indications of this system which includes labeling changes. There are no design changes from the legally marketed system in which safety and effectiveness were already confirmed under K142680 except for the software changes.

VIII. Summary of Clinical Testing
A review of Capsule Endoscopy (CE) clinical literature was conducted in order to show the safety and efficacy of the reference device, Given Imaging’s PillCam™ SB1 (PillCam™ M2A), in the evaluation of iron-deficiency anemia (IDA), obscure gastrointestinal bleeding (OGIB), and Crohn’s disease (CD). In support of the expanding indications for use and desired marketing claims, the following is a summary of referenced literature.

A sub-set of the studies in the Koulaouzidis meta-analysis that focused exclusively on IDA patients (four studies, 264 IDA patients)1,2,3,4, as opposed to IDA patients within the entire cohort receiving CE, revealed a higher diagnostic yield of 66.6% (95% CI, 61.0%-72.3%). All four of these studies explicitly defined IDA based on hemoglobin and ferritin measurements and were performed with the reference device. For comparison, the indication of OGIB for CE has a diagnostic yield ranging from <60% to >70% depending on the reported study size and timing of examination after a bleeding event, and the authors conclude that the overall positive diagnostic yield is ~50%.5 Both the reference (PillCamTM SB1) and subject (ENDOCAPSULE EC-10) devices are indicated for OGIB.

In the IDA studies, complications arising from the use of CE were rare and ranged from 0–5% of participants enrolled for all indications. The most common complication was retention of the capsule and in some cases this was noted to be caused by a stricture. The pooled complication rate (of those reporting complications) for the studies was 1.4% (40/2819). A 2010 systemic review estimated the overall retention rate for capsule endoscopy for all indications at 1.4%.6 A second, rare complication of CE is aspiration, occurring in 1 out of 800-1,000 procedures7, but this adverse event was not reported in the IDA studies. Therefore CE is safe to use for the indication of IDA, and IDA patients do not pose any unusual risk for complication.

Collectively, the comparable diagnostic yield of CE for IDA and OGIB, the similar findings under CE when performed for either of these two indications, the useful diagnostic information resulting from CE that can help modify care in IDA patients and the low rates of complication for CE in IDA patients shows that the reference (PillCam SB1) and subject (ENDOCAPSULE EC-10) devices can be used effectively and safely for the indication of IDA.
Multiple studies show that CE has been used in CD patients to safely and effectively provide diagnostic information or monitor lesions in patients with an established diagnosis. Chong et al.\(^8\) compared CE with push enteroscopy and enteroclysis in suspected and established CD patients. In patients with established CD, CE had a diagnostic yield of 77.3% (17/22 patients) compared with 13.6% for push enteroscopy and 19% for enteroclysis, and importantly lead to a change in clinical management in 76% (13/17) of the patients with positive CE findings. In patients with suspected CD, CE had a higher diagnostic yield of 19% compared with 0% for push enteroscopy and 6% for enteroclysis, but this was not statistically significant. Dubcenco et al.\(^9\) demonstrated that CE has high diagnostic accuracy with 89.6% sensitivity and 100% specificity when compared with histopathology results in a group of 39 patients with established or suspected CD. In this same study, CE had a diagnostic yield of 66.6%, compared with 20.5% for small bowel radiology. In patients with established CD undergoing CE following ileocolonic surgery, CE had diagnostic findings in 68% of patients and therapeutic modification could be recommended in 72.7% of the patients.\(^10\) Lastly, in consecutive established CD patients, CE revealed diagnostic findings in 60.9% of patients while enteroclysis showed diagnostic findings in 29.3%.\(^11\) In 24% of all patients that underwent CE, therapy was changed and all improved clinically. Diagnostic findings in all of the studies included features such as aphthous mucosal lesions, ulcers, luminal narrowing, erythema, villous denudation, erosions and mucosal scarring. These results and the remaining studies establish that the reach of CE and the sensitivity of this procedure for subtle mucosal changes of the small intestine make it an effective tool for evaluation of lesions consistent with CD.

Collectively, the high diagnostic yield and sensitivity/specificity (when reported) of CE in CD patients, the similar performance of CE compared with other diagnostic modalities commonly used in the CD workup, the useful diagnostic information resulting from CE that can help modify care in CD patients, and the low rates of complication for CE in CD patients shows that the reference (PillCam SB1) and subject (ENDOCAPSULE EC-10) devices can be used effectively and safely for the indication of CD.

IX. Conclusion

Based on the technological characteristics and clinical performance of the devices, Olympus believes that the OLYMPUS SMALL INTESTINAL CAPSULE ENDOSCOPE SYSTEM and the cited predicate device are substantially equivalent and do not change the scientific technology.

The proposed indications for use is expanding the device description to permit use for visualization and monitoring of additional disease states. Therefore, the subject device has essentially the same indications for use as the predicate device.