

SEP 14 2007

October 20, 2006

**510(k) SUMMARY**  
**OLYMPUS CAPSULE ENDOSCOPE SYSTEM**

**Section 1 General Information**

- **Applicant** OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan  
Establishment Registration No.: 8010047
- **Official Correspondent** Laura Storms-Tyler  
Executive Director  
Regulatory Affairs & Quality Assurance  
Olympus America Inc.  
3500 Corporate Parkway  
PO Box 610  
Center Valley, PA 18034-0610, USA  
Phone: 484-896-5688  
FAX: 484-896-7128  
Email: Laura.storms-tyler@olympus.com  
Establishment Registration No.: 2429304
- **Manufacturer** OLYMPUS MEDICAL SYSTEMS CORP.  
34-3 Hirai, Hinode-machi Nishitama-gun  
Tokyo, Japan 190-0182  
Establishment Registration Number: 3003637092

**Section 2 Device Identification**

- **Device Name** OLYMPUS CAPSULE ENDOSCOPE SYSTEM
- **Common Name** Capsule Imaging System
- **Regulation Number** 21 CFR 876.1300
- **Regulation Name** Ingestible Telemetric Gastrointestinal Capsule Imaging System
- **Regulatory Class** II
- **Product Code** 78NZE
- **Classification Panel** Gastroenterology and urology
- **Reason for Premarket Notification**

OLYMPUS MEDICAL SYSTEMS CORP. proposes to establish the safety and effectiveness of the capsule device for visualization of the small intestine.

■ **Compliance with Requirements of FD&C Act §514**

Performance Standard: None established under Section 514 of FD&C Act for Capsule Endoscope System.

Voluntary Standard: Reference is made in submission.

FDA Guidance: Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA (November 28, 2001)

■ **Predicate Device Information**

No.	510(k) No.	Device Name	Manufacturer
1	K010312	Given® Diagnostic Imaging System	Given Imaging Ltd.
2	K020341	Given® Diagnostic System	Given Imaging Ltd.
3	K022362	Given® Diagnostic System	Given Imaging Ltd.
4	K022980	Given® Diagnostic System	Given Imaging Ltd.
5	K031033	Given® Diagnostic System	Given Imaging Ltd.
6	K060805	Given® Diagnostic System	Given Imaging Ltd.

**Section 3 Device Description**

The OLYMPUS CAPSULE ENDOSCOPE SYSTEM consists of a capsule (OLYMPUS EC TYPE 1), Recorder unit (OLYMPUS RE-1), Antenna lead set (MAJ-1474), Real-time viewer(OLYMPUS VE-1) and Workstation(OLYMPUS WS-1). The composition and features of the devices described below are identical to those of the predicate device.

The Olympus capsule (OLYMPUS EC TYPE 1), has an outer diameter 11mm, a total length 26 mm, and is designed and manufactured with polymer composites that are biocompatible and provide sufficient tolerance to exposure to body fluids (digestive tract juice) and external compression forces.

The clear top cover contains a compact objective lens in front of the charge coupled device (CCD). 6 white light emitting diodes (LEDs) are allocated around the objective lens. The exterior package contains operational circuits for the CCD and LEDs and a radio transmitter and an antenna for radio transmission. In addition, this section of the capsule contains two silver oxide batteries to power the circuit within the capsule.

Recorder unit (OLYMPUS RE-1) is used in combination with Antenna lead set (MAJ-1474), which has 8 antenna pads for receiving the signals from the ingested capsule and for recording the data. The Recorder unit is powered by a detachable battery pack (specific for the Recorder unit) and is capable of receiving image data from the capsule for up to approximately 8-hours and record this data into the Compact Flash (CF) memory card. The Recorder unit has a display panel for displaying patient ID, battery pack level, etc.

Each 8-antenna pads of the Antenna lead set are to be inserted into the Antenna lead cover (MAJ-1470), which has a peel away tab, which exposes an adhesive side. The covered Antenna leads are secured onto the patient's abdominal area according to a labeling diagram provided in the labeling.

The Recorder unit is inserted into a pouch on the recorder unit harness. This unit is powered by the battery pack enabling the patient to move freely about during the endoscopic examination.

The Real-time viewer (OLYMPUS VE-1) is a compact monitoring unit that permits real-time display of recorded images on its color LCD by two different means and user options: receiving signals directly from the capsule (by means of an antenna in the Real-time viewer) as well as decoding signals from the Recorder Unit. The Real-time viewer is powered by a battery pack and is portable.

The battery charger (MAJ-1476) is used for charging of the battery pack and is not intended for use during the endoscopic examination.

The Workstation (OLYMPUS WS-1) is composed of a personal computer workstation installed with proprietary EndoCapsule Software), a LCD monitor and printer. An additional software CD (EndoCapsule software light) will be provided with the workstation. The EndoCapsule software light is provided for operator convenience, whereby the user can install this software on their own personal computer and view patient image data from the DVDs created by the Workstation WS-1.

The Workstation facilitates the downloading of endoscopic image data recorded in the Recorder unit to the Workstation hardware for observation of patient image data on the LCD monitor. It also provides the following functions such as initialization of the Recorder unit via the recorder unit cradle; image display as a pseudo-animation in 1-25fps; display/store images selected by the user as thumbnail data; user development and printing of diagnostic reports with pictures; image/video clip export; and data storage to a DVD from the Workstation's hard drive archive of the patient image file. In addition, the image processing function of the Workstation hardware offers the following user selectable software functions:

- Red Color Detection Function  
Software feature which highlights frames suspicious for blood or red lesions based upon analysis of red pixels within the image – Average Color Bar Calculates the average RGB colors of an image and displays the averaged color composite as a color line.
- Auto Speed Adjustment  
Automatically adjusts the speed of frame display based upon an analysis of slow image movement.

#### **Section 4 Indications for Use**

The OLYMPUS CAPSULE ENDOSCOPE SYSTEM has been designed to be used for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

#### **Section 5 Conclusion**

When compared to the predicate devices, OLYMPUS CAPSULE ENDOSCOPE SYSTEM is equivalent in intended use, method of operation, material, and design to the predicate device and has been demonstrated to be both safe and effective.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 14 2007

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

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Vice President  
Regulatory Affairs & Quality Assurance  
Olympus America, Inc.  
3500 Corporate Parkway  
P.O. Box 610  
CENTER VALLEY PA 18034-0610

Re: K063259  
Trade/Device Name: OLYMPUS CAPSULE ENDOSCOPE SYSTEM  
Regulation Number: 21 CFR §876.1300  
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system  
Regulatory Class: II  
Product Code: NEZ  
Dated: June 15, 2007  
Received: June 18, 2007

Dear Ms. Storms-Tyler:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



*Protecting and Promoting Public Health*

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); 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.

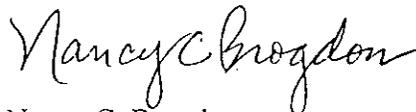
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K063259

Device Name: OLYMPUS CAPSULE ENDOSCOPE SYSTEM

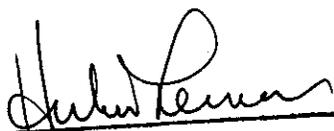
Indications for Use:

The OLYMPUS CAPSULE ENDOSCOPE SYSTEM has been designed to be used for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas.

Prescription Use  AND/OR Over-The-Counter Use  
(Part 21 CFR 801 Subpart D) (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)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K063259