K083155
pg 1 of 4

OLYMPUS

510(k) SUMMARY

HD CAMERA HEAD OTV-S7ProH-HD-L08E

JAN 13 2009

October 15, 2008

1 General Information

- Applicant:

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

- Official Correspondent:

Stacy Abbatiello Kluesner, RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5405
FAX: 484-896-7128
Email: stacy.kluesner@olympus.com
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 Trade Name: HD CAMERA HEAD OTV-S7ProH-HD-L08E
- Common Name: CAMERA HEAD
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/urology
- Product Code: KOG - Endoscope And/Or Accessories
  NWB - Endoscope, Accessories, Narrow Band Spectrum

3 Predicate Device Information

The following table shows the primary components of the subject devices and the devices to which we claim substantial equivalence (predicate devices).

Table 14-1. Primary Components & Predicate Devices

Subject Devices (Part of this submission)	Predicate Devices	PD's 510(k) No.
HD CAMERA HEAD OTV-S7ProH-HD-L08E	Camera Head for rigid endoscopes (with Auto focus) MH-972I	K955404

4 Device Description

HD CAMERA HEAD OTV-S7ProH-HD-L08E is an imaging device used with specified Olympus video system center, light source, endoscope, and other ancillary equipment for observation of endoscopic image on a video monitor.

The new camera head is basically identical to predicate device shown in Table 14-1 in intended use, and similar in specifications, performance.

5 Indications for Use

This camera head has been designed to be used with the CV-180 EXERA II video system center or OTV-S7Pro VISERA Pro video system center, endoscopes, light sources, video monitors and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.

6 Comparison of Technological Characteristics

The HD CAMERA HEAD OTV-S7ProH-HD-L08E is basically identical to the predicate device in intended use except for the limitation of the application to the bladder, urethra, ureter, and kidney, and similar in specifications except for addition of the Narrow Band Imaging function, embedded Remote Control Switches, and L-shaped configuration. Comparison between the subject and predicate device is shown in Table 14-2.

K083155
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Table 14-2. Comparison of Specifications

Subject Device : HD CAMERA HEAD OTV-S7ProH-HD-L08E

Predicate Device : Camera Head for rigid endoscopes (with Auto focus) MH-972I (K955404)

Item	Specifications	Subject Device OTV-S7ProH-HD-L08E	Predicate Device MH-972I
Dimension	Camera Head	O.D. 21mm x 83mm (from mount surface) L-shape	O.D. 40mm x 104mm (from mount surface) Straight shape
	Cable	O.D. 3.3mm x 4m	O.D. 6.6mm x 4m
	Weight	60g (excluding cable)	100g (excluding cable)
	Video plug	Card-edge type connector	Round shape type connector
	Remote control switches	Embedded	Separated
Observation	Pickup System	Interline type CCD solid-state image pickup	Interline type CCD solid-state image pickup
	Auto Iris	Not available	Available
	Narrow Band Imaging (NBI) function	Available	Not available
Operating Environment	Ambient Temperature	10 to 40°C	10 to 40°C
	Relative Humidity	30 to 85 %	30 to 85 %
	Atmospheric Pressure	700 to 1060 hPa	700 to 1060 hPa
Reprocessing	Cleaning	Immersible in detergent solution without water-resistant cap	Immersible in detergent solution with a water-resistant cap
	Disinfection	Immersible in disinfectant solution without water-resistant cap	Immersible in disinfectant solution with a water-resistant cap
	Sterilization	Ethylene oxide gas sterilization	Ethylene oxide gas sterilization
Patient contacting material	-	No patient contacting material	No patient contacting material

K083155

pg 4 of 4

7 Conclusion

When compared to the predicate device, the HD CAMERA HEAD OTV-S7ProH-HD-L08E does not incorporate any significant changes in intended use, method of operation, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2009

OLYMPUS MEDICAL SYSTEMS CORP.
% Stacy Abbatiello Kluesner, RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K083155
Trade/Device Name: HD CAMERA HEAD OTV-S7ProH-HD-L08E
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: October 23, 2008
Received: October 29, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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.

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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting 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): K083155

Device Name: **HD CAMERA HEAD OTV-S7ProH-HD-L08E**

Indications for Use:

This camera head has been designed to be used with the CV-180 EXERA II video system center or OTV-S7Pro VISERA Pro video system center, endoscopes, light sources, video monitors and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.

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 K083155