K062049
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OLYMPUS

510(k) SUMMARY

EVIS EXERA II 180 SYSTEM

SEP 22 2006

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.
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Center Valley PA 18034-0610
Phone: (484) 896-5688
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Email: Laura.storms-tyler @olympus.com
Establishment Registration No: 2429304

- Manufacturer

Light source/Video system center:

SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

Cysto-Nephroscopes:

AIZU OLYMPUS CO., LTD.
500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No: 9610595

- Date Prepared: June 27, 2006

2. Device Identification

- Device Name: EVIS EXERA II 180 SYSTEM
- Common Name: Endoscopic Video Imaging System
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: NWB and FAJ
- Classification Panel: Gastroenterology/Urology

3. Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the primary components (part of this submission) of the EVIS EXERA II 180 System and each device to which we claim substantial equivalence (predicate device).

Table 16-1. Primary Components & Predicate Devices of the EVIS EXERA II 180 System

Subject Device (Part of this Submission)	Predicate Device	PD's 510(k) No.
EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180	EVIS EXERA XENON LIGHT SOURCE OLYMPUS CLV-160A	K051645
EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180	EVIS EXERA VIDEO SYSTEM CENTER OLYMPUS CV-160A	
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	VISERA CYSTOVIDEOSCOPE OLYMPUS CYF TYPE V	K021074
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE VA2	VISERA CYSTOVIDEOSCOPE OLYMPUS CYF TYPE VA	
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS XCYF TYPE VQ		

4. Device Description

The EVIS EXERA II 180 System consists of Olympus camera heads, endoscopes, video system center, light source, monitors, endo-therapy accessories and other ancillary equipment. This system is intended for endoscopic diagnosis, treatment and video observation of the bladder, urethra, ureter, and kidney.

The primary components of the subject system, which are part of this submission, are:

- EVIS EXERA II Xenon Light Source Olympus CLV-180,
- EVIS EXERA II Video System Center Olympus CV-180,
- VISERA Cysto-Nephro Videoscope Olympus CYF type V2, CYF type VA2, and XCYF type VQ (hereinafter referred to as CYF-V2, CYF-VA2 and XCYF-VQ)

The EVIS EXERA II Xenon Light Source Olympus CLV-180 is intended for endoscopic diagnosis, treatment and video observation. The CLV-180 is substantially identical to the predicate device, EVIS EXERA Xenon Light Source CLV-160A cleared under K051645 except that the device size has been slightly changed. The CLV-180 has an optional filter which allows the user to enhance endoscopic white light images by selective processing of green and blue light. This feature, referred to as Narrow Band Imaging (NBI), employs an optical filter to filter the white light spectrum, changing it from a broad band to a narrow band. Both an endoscopic image by standard white light illumination and that by NBI illumination can be obtained. The user can select either the standard observation mode by pressing the scope switch on the scope or the NBI mode switch on the CLV-180. In comparison to conventional white light observation, NBI observation provides greater visual contrast of the surface structure and fine capillary patterns of the mucous membranes.

The EVIS EXERA II Video System Center Olympus CV-180 is a video processing system intended for use with Olympus endoscopes such as the subject endoscopes. The CV-180 Video System Center contains the video signal processing technology which enables the

endoscope to illuminate, enhance, view, record and transmit video data of endoscopic images. The CV-180 is identical to the predicate device, EVIS EXERA Video System Center CV-160A, cleared under K051645 except that the device size has been slightly changed.

The CV-180 incorporates the following features:
1. The CV-180 is compatible with any specified Olympus flexible, both video and fiberoptic, and rigid endoscopes.
2. The CV-180 processes the NBI image, generated by the CLV-180 light source and captured by the endoscope's Charged Coupled Device (CCD), creating an enhanced image of the tissue's vasculature.

Both the CLV-180 and CV-180 can be used with any specified Olympus flexible and rigid endoscope models, including gastroscopes, ultrasound gastroscopes, duodenoscopes, colonoscopes, sigmoidscopes, choledochoscopes, bronchoscopes, rhino-laryngoscopes, tracheal intubation scopes, transnasal esophago scopes, hysteroscopes, cystoscopes, ureterorenoscopes, laparo-thoracoscopes, for conventional white light endoscopy. The flexible endoscopes which are the subject of this premarket notification are cysto-nephroscope models listed in Table 16-1.

Additionally, when they are combined with the new cysto-nephro videoscopes (CYF-V2, CYF-VA2, and XCYF-VQ), both an endoscopic image by white light illumination and that by NBI illumination can be obtained. The user can select either the NBI mode or normal mode by pressing the scope switch on the scope or the NBI mode switch on the CLV-180; the NBI filter in the CLV-180 is inserted on the light axis when the NBI mode is selected.

The new endoscopes are basically identical to each predicate device shown in Table 16-1 in intended use, and similar in specifications, performance and materials. The CV-180 identifies an NBI-compatible scope when it is connected by using the Scope ID function provided with the scopes.

5. Indications for Use

EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180
This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180
This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, XCYF TYPE VQ
These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.

6. Comparison of Technological Characteristics

Each primary component of the EVIS EXERA II 180 System is basically identical to its predicate device in intended use, and similar in specifications except for the addition of the NBI function. Comparison between the subject and predicate devices is shown in Table 16-2 to 16-5.

Table 16-2. Comparison of Specifications
Subject Device: EVIS EXERA II Xenon Light Source Olympus CLV-180
Predicate Device: EVIS EXERA Xenon Light Source Olympus CLV-160A (K051645)

Specifications	Subject Device CLV-180	Predicate Device CLV-160A
Power Supply	100-120V～±10%, 50/60 Hz±1Hz	100-240V～±10%, 50/60Hz±1Hz
Over-current Protection	Same as PD.	Fuse type
Input Current	Same as PD.	500VA (at observation)
Size	383(W)×162(H)×536(D)mm	381(W)×162(H)×536(D)mm
Weight	Same as PD.	15.4kg
Compatible Endoscopes	Same as PD.	Videoscope, Fiberscope, Rigid scope
Examination Lamp	Same as PD.	Xenon short-arc lamp (ozone-free)300W
Average Lamp Life	Same as PD.	Approximately 500 hours of continuous use
Emergency Lamp	Same as PD.	Halogen lamp 12V 35W
Average Emergency Lamp Life	Same as PD.	Approximately 500 hours
NBI Filter	Same as PD.	Provided.
Brightness Control	Same as PD.	Automatic and Manual
Automatic Exposure	Same as PD.	17 steps
Photography Function	Same as PD.	Not provided.
Air Feeding	Same as PD.	4 levels available (off, low, mid, high)
Air Feeding Pump	Same as PD.	Diaphragm type pump
System Connector	Same as PD.	Provided
Foot Switch Connector	Same as PD.	Provided
CV Connector	Same as PD.	Provided
Cooling Air Direction	Same as PD.	Rear
Type of Protection against Electric Shock	Same as PD.	Class I
Degree of Protection against Electric Shock of Applied Part	Same as PD.	TYPE BF or CF applied part (Depend on applied part)
Applicable Standard	Same as PD.	UL60601-1

Table 16-3. Comparison of Specifications

Subject Device: EVIS EXERA II Video System Center Olympus CV-180

Predicate Device: EVIS EXERA Video System Center Olympus CV-160A (K051645)

Specifications		Subject Device CV-180	Predicate Device CV-160A
Power Supply		Same as PD.	100-240V～±10%、50/60Hz±1Hz
Over-current Protection		Same as PD.	Fuse type
Input Current		Same as PD.	150VA
Size		382(W)×91(H)×490 (D)mm	370(W)×91(H)×462 (D)mm
Weight		10 kg	10.6 kg
Compatible Endoscopes		Same as PD.	・Fiber/rigid scope via camera head ・Videoscope
Observation	Video Signal Output	Same as PD.	RGB:3 Y/C:4 VBS:4 HDTV:1
	Auto White Balance	Same as PD.	Automatically adjusted using the white balance switch. At the time of connection with the scope in which Scope ID is provided, compensation is performed automatically.
	Standard Color Chart Output	Same as PD.	Color bar image
	Color Tone Adjustment	Same as PD.	R: ±8 steps B: ±8 steps CHROMA：±8steps
	Automatic Gain Control (AGC)	Same as PD.	MAX gain: 18dB
	Image Enhancement	Same as PD.	Edge enhancement: [OFF] [Low] [Med] [High] 4 levels available Structure enhancement:[OFF] [Low] [Med] [High] 4 levels available
	Iris Mode Selection	Same as PD.	AUTO／PEAK EXPOSURE Electrical shutter
	Optical Zoom	Same as PD.	×1/×1.2 /×1.5: 3-Mode
	NBI Observation	Same as PD.	NBI function
	Picture in Picture	Same as PD.	The image of an external device connected to this instrument is displayed on the main monitor together with the endoscopic image.
Communication with Scope		Same as PD.	Provided
Foot Switch Connector		Same as PD.	Provided
Record to Memory Card		Same as PD.	Provided
Type of Protection against Electric Shock		Same as PD.	Class I
Degree of Protection against Electric Shock of Applied Part		Same as PD.	TYPE BF or CF applied part (Depend on applied part)
Applicable Standard		Same as PD.	UL60601-1

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Table 16-4. Comparison of Specifications
Subject Device: VISERA Cysto-Nephro Videoscope Olympus CYF type V2/VA2
Predicate Device: VISERA Cystovideoscope Olympus CYF type V/VA (K021074)

Specifications	Subject Device CYF-V2/VA2		Predicate Device CYF-V/VA	
Field of View	120°		120°	
Depth of Field	3-50 mm		3-50 mm	
Direction of View	0° Forward Viewing		0° Forward Viewing	
Type of CCD Chip	Color		Color	
Outer Diameter of Distal End	ϕ 4.8 mm bullet-shaped		ϕ 5.4 mm	
Outer Diameter of Insertion Tube	ϕ 5.4mm		ϕ 5.4 mm	
Suction Function	CYF-V2	CYF-VA2	CYF-V	CYF-VA
	Not Provided	Provided	Not Provided	Provided
Bending Section Angulation UP/DOWN	210° /120°		210° /120°	
Working Length	380 mm		380 mm	
Inner Diameter of Instrument Channel	ϕ 2.2 mm		ϕ 2.2 mm	

Table 16-5. Comparison of Specifications
Subject Device: VISERA Cysto-Nephro Videoscope Olympus XCYF type VQ
Predicate Device: VISERA Cystovideoscope Olympus CYF type V/VA (K021074)

Specifications	Subject Device XCYF-VQ	Predicate Device CYF-V/VA	
Field of View	120°	120°	
Depth of Field	3-20 mm	3-50 mm	
Direction of View	0° Forward Viewing	0° Forward Viewing	
Type of CCD Chip	Color	Color	
Outer Diameter of Distal End	ϕ 5.9 mm	ϕ 5.4 mm	
Outer Diameter of Insertion Tube	ϕ 5.5 mm	ϕ 5.4 mm	
Suction Function	Provided	CYF-V	CYF-VA
		Not Provided	Provided
Bending Section Angulation UP/DOWN	210° /120°	210° /120°	
Working Length	380 mm	380 mm	
Inner Diameter of Instrument Channel	ϕ 2.0 mm	ϕ 2.2 mm	

6. Conclusion

When compared to the predicate devices, the EVIS EXERA II 180 System does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the system.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 22 2006

Ms. Laura Storms-Tyler
Executive Director, Regulatory and Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K062049
Trade/Device Name: EVIS EXERA II 180 System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NWB
Dated: September 11, 2006
Received: September 13, 2006

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.

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

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): K062049

Device Name: EVIS EXERA II 180 SYSTEM

Indications For Use:

EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180
This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180
This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, XCYF TYPE VQ
These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, endo-therapy accessories, 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)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062049