K061313

AUG 8 0 2006

510(k) SUMMARY

EVIS EXERA II 180 SYSTEM

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
Phone: 484-896-5688
FAX: 484-896-7128
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

Bronchoscope/
Rhino-Laryngoscope:

Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595

Suction valve/Biopsy valve:

OLYMPUS MEDICAL SYSTEMS CORP. Hinode Plant
34-3 Hirai Hinode-machi, Nishitama-gun,
Tokyo, Japan 190-0182
Establishment Registration No.: 3003637092

■ Date Prepared

April 1, 2006

K061313

2. Device Identification

- Device Name: EVIS EXERA II 180 System
- Common Name: Endoscopic Video Imaging System
- Class: II
- Classification:

Table 16-1. Classification of the EVIS EXERA 160A System

Regulation Number	Regulation Name	Product Code	Classification Panel
874. 4680	Bronchoscope (flexible or rigid) and accessories	EOQ- Bronchoscope (Flexible or rigid)	Ear, Nose & Throat
874.4760	Nasopharyngoscope (flexible or rigid) and accessories	EOB- Nasopharyngoscope (Flexible or rigid)	
876.1500	Endoscope and accessories	NWB- Endoscope, accessories, narrow band spectrum	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 16-2. 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	
EVIS EXERA II BRONCHOVIDEOSCOPE OLYPUS BF TYPE P180	EVIS EXERA BRONCHOVIDEOSCOPE OLYPUS BF TYPE160	K023984
EVIS EXERA II BRONCHOVIDEOSCOPE OLYPUS BF TYPE Q180		
EVIS EXERA II BRONCHOVIDEOSCOPE OLYPUS BF TYPE 1T180	EVIS EXERA BRONCHOVIDEOSCOPE OLYPUS BF TYPE 1T160	
VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE V2	VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE V	K031648
VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS XENF TYPE VTY1	VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE VT	K052452

K061313

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 airways, tracheobronchial tree, nasal lumens and airway anatomy.

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,
- EVIS EXERA II Bronchovideoscope Olympus BF -P180, BF -1T180, BF -Q180
- VISERA Rhino-Laryngo Videoscope Olympus ENF-V2, XENF-VTY1

The EVIS EXERA II Xenon Light Source Olympus CLV-180 is intended for endoscopic diagnosis, treatment and video observation. The CLV-180 is 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 endoscope.
2. The CV-180 processes the NBI image, generated by the CLV-160A 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 ridid 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 bronchoscope and rhino-laryngoscope models listed in Table 16-2.

Additionally, when they are combined with the new bronchovideoscopes (BF-P180, BF-1T180, BF-Q180), and rhino-laryngo videoscopes (ENF-V2, XENF-VTY1), 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-160A; 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 16-2 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.

EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180, BF TYPE 1T180, BF TYPE Q180
These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE V2
This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis within the nasal lumens and airway anatomy (including nasopharyngeal and trachea).

VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS XENF TYPE VTY1
This instrument has 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 nasal lumens and airway anatomy (including nasopharyngeal and trachea).

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 16-3 to 16-9.

K061313

Table 16-3. 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

K061313

Table 16-4. 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

Table 16-5. Comparison of Specifications
Subject Device: EVIS EXERA II Bronchovideoscope BF-P180
Predicate Device: EVIS EXERA Bronchovideoscope BF-160 (K023984)

Specifications	Subject Device BF-P180	Predicate Device BF-160
Field of View	120°	120°
Depth of Field	3-100 mm	3-100 mm
Direction of View	0° Forward Viewing	0° Forward Viewing
Type of CCD	Color	Color
Outer Diameter of Distal End	4.9 mm	5.3 mm
Outer Diameter of Insertion Tube	4.9 mm	5.2 mm
Bending Section Angulation UP/DOWN	180° /130°	180° /130°
Working Length	600 mm	600 mm
Inner Diameter of Instrument Channel	2.0 mm	2.0 mm

Table 16-6. Comparison of Specifications
Subject Device: EVIS EXERA II Bronchovideoscope BF-1T180
Predicate Device: EVIS EXERA Bronchovideoscope BF-1T160 (K023984)

Specifications	Subject Device BF-1T180	Predicate Device BF-1T160
Field of View	120°	120°
Depth of Field	3-100 mm	3-100 mm
Direction of View	0° Forward Viewing	0° Forward Viewing
Type of CCD	Color	Color
Outer Diameter of Distal End	6.0 mm	6.0 mm
Outer Diameter of Insertion Tube	6.0 mm	6.0 mm
Bending Section Angulation UP/DOWN	180° /130°	180° /130°
Working Length	600 mm	600 mm
Inner Diameter of Instrument Channel	3.0 mm	2.8 mm

K061313

Table 16-7. Comparison of Specifications
Subject Device: EVIS EXERA II Bronchovideoscope BF-Q180
Predicate Device: EVIS EXERA Bronchovideoscope BF-160 (K023984)

Specifications	Subject Device BF-Q180	Predicate Device BF-160
Field of View	120°	120°
Depth of Field	3-100 mm	3-100 mm
Direction of View	0° Forward Viewing	0° Forward Viewing
Type of CCD	Color	Color
Outer Diameter of Distal End	5.5 mm	5.3 mm
Outer Diameter of Insertion Tube	5.1 mm	5.2 mm
Bending Section Angulation UP/DOWN	180° /130°	180° /130°
Working Length	600 mm	600 mm
Inner Diameter of Instrument Channel	2.0 mm	2.0 mm

Table 16-8. Comparison of Specifications
Subject Device: VISERA Rhino-Laryngo Videoscope Olympus ENF type V2
Predicate Device: VISERA Rhino-Laryngo Videoscope Olympus ENF type V (K031648)

Specifications	Subject Device ENF-V2	Predicate Device ENF-V
Field of View	90°	90°
Depth of Field	5-50mm	5-50mm
Direction of Forward View	0°	0°
Type of CCD Chip	Color	Color
Outer Diameter of Distal End	ϕ 3.2mm	ϕ 3.9mm
Outer Diameter of Insertion Tube	ϕ 3.4mm	ϕ 3.9mm
Bending Section Angulation	Up: 130° Down: 130°	Up: 130° Down: 130°
Working Length	300mm	365mm

To Laura: The ENF-V2 and ENF-V do not have an instrument channel, so I have deleted this column.

K061313

Table 16-9. Comparison of Specifications
Subject Device: VISERA Rhino-Laryngovideoscope Olympus XENF type VTY1
Predicate Device: VISERA Rhino-Laryngovideoscope Olympus ENF type VT (K052452)

Specifications	Subject Device XENF-VTY1	Predicate Device ENF-VT
Field of View	90°	90°
Depth of Field	5-50mm	5-50mm
Direction of Forward View	0°	0°
Type of CCD Chip	Color	Color
Outer Diameter of Distal End	ϕ4.8mm	ϕ4.8mm
Outer Diameter of Insertion Tube	ϕ4.9mm	ϕ4.9mm
Bending Section Angulation	Up: 130° Down: 130°	Up: 130° Down: 130°
Working Length	365mm	365mm
Inner Diameter of Instrument Channel	ϕ2.0mm	ϕ2.0mm

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2006

Olympus America, Inc
c/o Laura Storms-Tyler
Executive Director, Regulatory Affairs and Quality Assurance
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034-0610

Re: K061313
Trade/Device Name: Olympus Evis Exera 180 System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ, EOB, NWB
Dated: August 1, 2006
Received: August 2, 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 (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 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 (240) 276-0115. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061313

Device Name: EVIS EXERA II 180 SYSTEM

Indications for Use:

VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE V2

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, display monitor, and other ancillary equipment for endoscopic diagnosis within the nasal lumens and airway anatomy (including nasopharyngeal and trachea).

VISERA RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF TYPE VTY1

This instrument has 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 nasal lumens and airway anatomy (including nasopharyngeal and trachea).

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)

Karen A Burkhart

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K061313

Indications for Use

510(k) Number (if known):

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.

EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180, BF TYPE 1T180, BF TYPE Q180
These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

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 Ophthalmic Ear, Nose and Throat Devises

510(k) Number K061313

Prescription Use
(Per 21 CFR 801.109)