K100584

JUL - 2 2010

510(k) SUMMARY

EVIS EXERA II 180 SYSTEM

February 26, 2010

1 General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Establishment Registration No.: 8010047
■ Official Correspondent:	Stacy Abbatiello Kluesner, M.S., 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
■ 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
Gastrointestinal videoscope/ Colonovideoscope:	Aizu Olympus Co., Ltd. 500 Aza-Muranishi, Ooaza-lidera, Monden-cho, Aizuwakamatsu-shi, Fukushima, Japan 965-8520 Establishment Registration No.: 9610595

2 Device Identification

■ Device Trade Name:	EVIS EXERA II 180 SYSTEM
■ Common Name:	Endoscopic Video Imaging System
■ Regulation Number:	21 CFR 876.1500
■ Regulation Name:	Endoscope and accessories
■ Regulatory Class:	II
■ Classification Panel:	Gastroenterology/Urology
■ Product Code:	NWB, FDF, FDS

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 (Hereinafter referred to as CLV-180) (K061313, K062049)	EVIS EXERA Xenon Light Source Olympus CLV-160A	K051645
EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180 (Hereinafter referred to as CV-180) (K061313, K062049)	EVIS EXERA Video System Center Olympus CV-160A	K051645
EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE N180 (Hereinafter referred to as GIF-N180)	EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2	K051645
EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE XP180N (Hereinafter referred to as GIF-XP180N)	EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2	K051645
EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE Q180 (Hereinafter referred to as GIF-Q180)	EVIS EXERA Gastrointestinal Videoscope XGIF-Q160Y5	K051645
EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE H180 (Hereinafter referred to as GIF-H180)	EVIS EXERA Gastrointestinal Videoscope XGIF-H160Y2	K051645
EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL (Hereinafter referred to as CF-Q180AL)	EVIS EXERA Colonovideoscope XCF-Q160W6L	K051645
EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AI (Hereinafter referred to as CF-Q180AI)	EVIS EXERA Colonovideoscope XCF-Q160W6L	K051645
EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AL (Hereinafter referred to as CF-H180AL)	EVIS EXERA Colonovideoscope XCF-H160AY2L	K051645
EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AI (Hereinafter referred to as CF-H180AI)	EVIS EXERA Colonovideoscope XCF-H160AY2L	K051645
EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE Q180AL (Hereinafter referred to as PCF-Q180AL)	EVIS EXERA Colonovideoscope XPCF-Q160AY2L	K051645

EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AL (Hereinafter referred to as PCF-H180AL)	EVIS EXERA Colonovideoscope XPCF-Q160AY2L	K051645
EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AI (Hereinafter referred to as PCF-H180AI)	EVIS EXERA Colonovideoscope XPCF-Q160AY2L	K051645

4 Device Description

The EVIS EXERA II 180 SYSTEM consists of Olympus camera heads, endoscopes, video system center, light source, monitors, EndoTherapy accessories and other ancillary equipment. This system is intended for endoscopic diagnosis, treatment and video observation of the upper and lower digestive tract.

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 GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE N180
- EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE XP180N
- EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE Q180
- EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE H180
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AI
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AL
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE H180AI
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE Q180AL (PEDIATRIC)
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE Q180AI (PEDIATRIC)
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AL (PEDIATRIC)
- EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS PCF TYPE H180AI (PEDIATRIC)

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. The user can select eihter the standard obsevation mode by pressing the scope switch on the scope or the filter mode switch on the CLV-180. In comparison to conventional white light observation, NBI observation provides the greater contrast of the surface 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 gastrointestinal videoscopes and colonovideoscopes. The CV-180 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.

videoscopes and colonovideoscopes. The CV-180 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 subject premarket notification is specific for gastrointestinal videoscopes and colonovideoscopes.

Additionally, when they are combined with the subject endoscopes, 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 light mode by pressing the scope switch on the scope or the filter 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 subject endoscopes are basically identical to each Olympus 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 sources, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE N180, OLYMPUS GIF TYPE XP180N

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy

and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach, and duodenum).

EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL, OLYMPUS CF TYPE Q180AI, OLYMPUS CF TYPE H180AL, OLYMPUS CF TYPE H180AI, OLYMPUS PCF TYPE Q180AL (Pediatric), OLYMPUS PCF TYPE Q180AI (Pediatric), OLYMPUS PCF TYPE H180AL (Pediatric), OLYMPUS PCF TYPE H180AI (Pediatric)

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

6 Comparison of Technological Characteristics

Each primary components of the EVIS EXERA II 180 SYSTEM is basically identical to its predicate device in intended use, and similar in specifications. Comparison between the subject and predicate devices is shown in Table 16-2 to 16-11. The clinical literatures provided in this submission support new sales promotional claims for Barrett's esophagus, colorectal polyp detection and histology prediction.

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 AC ±10%, 50/60 Hz ± 1Hz	100-240V AC±10%, 50/60 Hz ± 1Hz
Over-current Protection	Identical to the Predicate Device	Fuse type
Input Current	Identical to the Predicate Device.	500VA (at observation)
Size	383(W)×162(H)×536(D)mm	381(W)×162(H)×536(D)mm
Weight	Identical to the Predicate Device	15.4kg
Compatible Endoscopes	Identical to the Predicate Device	Videoscope Fiberscope Rigid scope
Examination Lamp	Identical to the Predicate Device	Xenon short-arc lamp (ozone-free)300W
Average Lamp Life	Identical to the Predicate Device	Approximately 500 hours of continuous use
Emergency Lamp	Identical to the Predicate Device	Halogen lamp 12V 35W
Average Emergency Lamp Life	Identical to the Predicate Device	Approximately 500 hours
NBI Filter	Identical to the Predicate Device	Provided
Brightness Control	Identical to the Predicate Device	Automatic and Manual
Automatic Exposure	Identical to the Predicate Device	17 steps
Photography Function	Identical to the Predicate Device	Not provided.
Air Feeding	Identical to the Predicate Device	4 levels available (off, low, mid,

Emergency Lamp	Identical to the Predicate Device	Halogen lamp 12V 35W
Average Emergency Lamp Life	Identical to the Predicate Device	Approximately 500 hours
NBI Filter	Identical to the Predicate Device	Provided
Brightness Control	Identical to the Predicate Device	Automatic and Manual
Automatic Exposure	Identical to the Predicate Device	17 steps
Photography Function	Identical to the Predicate Device	Not provided.
Air Feeding	Identical to the Predicate Device	4 levels available (off, low, mid, high)
Air Feeding Pump	Identical to the Predicate Device	Diaphragm type pump
System Connector	Identical to the Predicate Device	Provided
Foot Switch Connector	Identical to the Predicate Device	Provided
CV Connector	Identical to the Predicate Device	Provided
Cooling Air Direction	Identical to the Predicate Device	Rear
Type of Protection against Electric Shock	Identical to the Predicate Device	Class I
Degree of Protection against Electric Shock of Applied Part	Identical to the Predicate Device	TYPE BF or CF applied part (Depend on applied part)
Applicable Standard	Identical to the Predicate Device	UL60601-1

Table 16-3 Comparison of Specifications (1/2)

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		Identical to the Predicate Device	100-240V AC±10%, 50/60 Hz ± 1Hz
Over-current Protection		Identical to the Predicate Device.	Fuse type
Input Current		Identical to the Predicate Device.	150VA
Size		382(W)×91(H)×490 (D) mm	370(W)×91(H)×462 (D)mm
Weight		10 kg	10.6 kg
Compatible Endoscopes		Identical to the Predicate Device.	・Fiber/rigid scope via camera head ・Videoscope
Observation	Video Signal Output	Identical to the Predicate Device.	RGB:3 Y/C:4 VBS:4 HDTV:1
	Auto White Balance	Identical to the Predicate Device.	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	Identical to the Predicate Device.	Color bar image
	Color Tone Adjustment	Identical to the Predicate Device.	R: ±8 steps B: ±8 steps CHROMA : ±8steps
	Automatic Gain Control (AGC)	Identical to the Predicate Device.	Provided
	Image Enhancement	Identical to the Predicate Device.	Edge enhancement: [OFF] [Low] [Med] [High] 4 levels available Structure enhancement:[OFF] [Low] [Med] [High] 4 levels available
	Iris Mode Selection	Identical to the Predicate Device.	AUTO／PEAK EXPOSURE Electrical shutter
	Optical Zoom	Identical to the Predicate Device.	×1/×1.2 /×1.5: 3-Mode
	NBI Observation	Identical to the Predicate Device.	NBI function
	Picture in Picture	Identical to the Predicate Device.	The image of an external device connected to this instrument is displayed on the main monitor together with the endoscopic image.
Communication with Scope		Identical to the Predicate Device.	Provided
Foot Switch Connector		Identical to the Predicate Device.	Provided

Table 16-3 Comparison of Specifications (Continued, 2/2)
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
Record to Memory Card	Identical to the Predicate Device.	Provided
Type of Protection against Electric Shock	Identical to the Predicate Device.	Class I
Degree of Protection against Electric Shock of Applied Part	Identical to the Predicate Device.	TYPE BF or CF applied part (Depend on applied part)
Applicable Standard	Identical to the Predicate Device.	UL60601-1

Table 16-4 Comparison of Specifications
Subject Device: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE GIF-N180
Predicate Device: EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2 (K051645)

Specifications	Subject Device GIF-N180	Predicate Device XGIF-N160Y2
Field of View	Identical to the Predicate Device	120°
Depth of Field	Identical to the Predicate Device	3-100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	Identical to the Predicate Device	4.9mm
Outer Diameter of Insertion Tube	Identical to the Predicate Device	4.9mm
Bending Section Angulation	Identical to the Predicate Device	UP: 210° DOWN: 120°
Working Length	Identical to the Predicate Device	1100mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	2.0mm

Table 16-5 Comparison of Specifications

Subject Device: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE GIF-XP180N

Predicate Device: EVIS EXERA Gastrointestinal Videoscope XGIF-N160Y2 (K051645)

Specifications	Subject Device GIF-XP180N	Predicate Device XGIF-N160Y2
Field of View	Identical to the Predicate Device	120°
Depth of Field	Identical to the Predicate Device	3-100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	5.5mm	4.9mm
Outer Diameter of Insertion Tube	5.5mm	4.9mm
Bending Section Angulation	UP: 210° DOWN: 90° RIGHT: 100° LFFT: 100°	UP: 210° DOWN: 120°
Working Length	Identical to the Predicate Device	1100mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	2.0mm

Table 16-6 Comparison of Specifications

Subject Device: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE GIF-Q180

Predicate Device: EVIS EXERA Gastrointestinal Videoscope XGIF-Q160Y5 (K051645)

Specifications	Subject Device GIF-Q180	Predicate Device XGIF-Q160Y5
Field of View	Identical to the Predicate Device	140°
Depth of Field	Identical to the Predicate Device	3-100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	Identical to the Predicate Device	8.8mm
Outer Diameter of Insertion	Identical to the Predicate Device	8.8mm
Bending Section Angulation	Identical to the Predicate Device	UP: 210° DOWN: 90° RIGHT: 100° LEFT: 100°
Working Length	Identical to the Predicate Device	1030mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	2.8mm

Table 16-7 Comparison of Specifications

Subject Device: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE GIF-H180

Predicate Device: EVIS EXERA Gastrointestinalvideoscope XGIF-H160Y2 (K051645)

Specifications	Subject Device GIF-H180	Predicate Device XGIF-H160Y2
Field of View	Identical to the Predicate Device	140°
Depth of Field	Identical to the Predicate Device	2-100mm
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	Identical to the Predicate Device	9.8mm
Outer Diameter of Insertion Tube	Identical to the Predicate Device	9.8mm
Bending Section Angulation	Identical to the Predicate Device	UP: 210° DOWN: 90° RIGHT: 100° LEFT: 100°
Working Length	Identical to the Predicate Device	1030mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	2.8mm

Table 16-8 Comparison of Specifications

Subject Device: EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE CF-Q180AL, CF-Q180AI

Predicate Device: EVIS EXERA Colonovideoscope XCF-Q160W6L (K051645)

Specifications	Subject Device CF-Q180AL, CF-Q180AI	Predicate Device XCF-Q160W6L
Field of View	Identical to the Predicate Device	170°
Depth of Field	Identical to the Predicate Device	3-100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	Identical to the Predicate Device	13.2mm
Outer Diameter of Insertion Tube	Identical to the Predicate Device	12.8mm
Bending Section Angulation	Identical to the Predicate Device	UP: 180° DOWN: 180° RIGHT: 160° LEFT: 160°
Working Length	CF-Q180AL: Identical to the Predicate Device CF-Q180AI: 1330mm	1680mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	3.7mm
Flexibility of Insertion Tube	Identical to the Predicate Device	Adjustable by the user.

Table 16-9 Comparison of Specifications
Subject Device: EVIS EXERA II COLONOVIDEOSCOPE CF-H180AL, CF-H180AI
Predicate Device: EVIS EXERA Colonovideoscope XCF-H160AY2L (K051645)

Specifications	Subject Device CF-H180AL, CF-H180AI	Predicate Device XCF-H160AY2L
Field of View	Identical to the Predicate Device	170°
Depth of Field	Identical to the Predicate Device	2 -100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	Identical to the Predicate Device	13.9mm
Outer Diameter of Insertion Tube	Identical to the Predicate Device	12.8mm
Bending Section Angulation	Identical to the Predicate Device	UP: 180° DOWN: 180° RIGHT: 160° LEFT: 160°
Working Length	CF-H180AL: Identical to the Predicate Device CF-H180AI: 1330mm	1680mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	3.7mm
Flexibility of Insertion Tube	Identical to the Predicate Device	Adjustable by the user.

Table 16-10 Comparison of Specifications
Subject Device: EVIS EXERA II COLONOVIDEOSCOPE PCF-Q180AL, PCF-Q180AI
Predicate Device: EVIS EXERA Colonovideoscope XPCF-Q160AY2L (K051645)

Specifications	Subject Device PCF-Q180AL, PCF-Q180AI	Predicate Device XPCF-Q160Y2L
Field of View	Identical to the Predicate Device	140°
Depth of Field	Identical to the Predicate Device	3-100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	Identical to the Predicate Device	11.3mm
Outer Diameter of Insertion Tube	Identical to the Predicate Device	11.5mm
Bending Section Angulation	Identical to the Predicate Device	UP: 180° DOWN: 180° RIGHT: 160° LEFT: 160°
Working Length	PCF-Q180AL: Identical to the Predicate Device PCF-Q180AI: 1330mm	1680mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	3.2mm
Flexibility of Insertion Tube	Identical to the Predicate Device	Adjustable by the user.

Table 16-11 Comparison of Specifications
Subject Device: EVIS EXERA II COLONOVIDEOSCOPE PCF-H180AL, PCF-H180AI
Predicate Device: EVIS EXERA Colonovideoscope XPCF-Q160AY2L (K051645)

Specifications	Subject Device PCF-H180AL, PCF-H180AI	Predicate Device XPCF-Q160Y2L
Field of View	Identical to the Predicate Device	140°
Depth of Field	2-100mm	3-100mm
Direction of Forward View	Identical to the Predicate Device	0°
Type of CCD	Identical to the Predicate Device	Color
Outer Diameter of Distal End	11.7mm	11.3mm
Outer Diameter of Insertion Tube	11.8mm	11.5mm
Bending Section Angulation	Identical to the Predicate Device	UP: 180° DOWN: 180° RIGHT: 160° LEFT: 160°
Working Length	PCF-H180AL: Identical to the Predicate Device PCF-H180AI: 1330mm	1680mm
Inner Diameter of Instrument Channel	Identical to the Predicate Device	3.2mm
Flexibility of Insertion Tube	Identical to the Predicate Device	Adjustable by the user.

7 Conclusion

When compared to the predicate device, 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 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Olympus Medical Systems Corporation
% Ms. Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
PO Box 610
CENTER VALLEY PA 18034-0610

JUL - 2 2010

Re: K100584
Trade/Device Name: EVIS EXERA II 180 System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: NWB, FDS, FDF
Dated: June 18, 2010
Received: June 22, 2010

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 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): K100584

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 sources, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100584

Indications for Use

510(k) Number (if known): K100584

Device Name: EVIS EXERA II 180 SYSTEM

Indications for Use:

EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE N180, OLYMPUS GIF TYPE XP180N

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for transoral or transnasal endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach, and duodenum).

EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE Q180, OLYMPUS GIF TYPE H180

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract (including the esophagus, stomach, and duodenum).

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100584

Indications for Use

510(k) Number (if known): K100584

Device Name: EVIS EXERA II 180 SYSTEM

Indications for Use:

EVIS EXERA II COLONOVIDEOSCOPE OLYMPUS CF TYPE Q180AL, OLYMPUS CF TYPE Q180AI, OLYMPUS CF TYPE H180AL, OLYMPUS CF TYPE H180AI, OLYMPUS PCF TYPE Q180AL (Pediatric), OLYMPUS PCF TYPE Q180AI (Pediatric), OLYMPUS PCF TYPE H180AL (Pediatric), OLYMPUS PCF TYPE H180AI (Pediatric),

These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon, and ileocecal valve).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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