OLYMPUS

K080403

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510(k) SUMMARY

EVIS EXERA II 180 SYSTEM

MAY 20 2008

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
Vice President
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway, PO Box 610
Center Valley PA 18034-0610
Phone: (484) 896-5688
Facsimile: (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

Duodenoscope:

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

- Date Prepared: February 8, 2008

2. Device Identification

- Device Name: XTJF-160AF Duodenoscope
- Common Name: Duodenoscope
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: NWB - Endoscope, accessories, narrow band spectrum
  FDT - Duodenoscope, Esophago Gastro
  KNT - Tubes, gastrointestinal (and accessories)
- Classification Panel: Gastroenterology/Urology

3. Legally Marketed Device to which Substantial Equivalence is Claimed

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

Table 15-1:
Primary Component & Predicate Device

Subject Device (part of this submission)	Predicate Device	PD's 510(k) No.
DUODENOVIDEOSCOPE XTJF TYPE Q160VF1	Duodenovideoscope XTJF-160AF	K024033

4. Device Description

The XTJF-Q160VF1 duodenoscope is a flexible video endoscope used for endoscopic diagnosis and treatment within the duodenum . The XTJF-Q160VF1 duodenoscope is basically identical to the predicate device, Olympus XTJF Type 160AF Duodenovideoscope, in intended use, specifications, performance. The optical system of the XTJF-Q160VF1 is a charge coupled device (CCD) based system, allowing endoscopic image display on a video monitor.

The new endoscope is basically identical to each predicate device shown in Table 15-1 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

DUODENOVIDEOSCOPE XTJF-Q160VF1
This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the duodenum.

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6. Comparison of Technological Characteristics

The XTJF-Q160VF1 is similar to the predicate device XTJF-160AF in specifications except for the material and optical system. Comparison between the subject and predicate devices is shown below.

Table 15-2. Comparison of Specifications
Subject Device: DUODENOVIDEOSCOPE XTJF TYPE Q160VF1
Predicate Device: Duodenovideoscope XTJF-160AF (K024033)

Specifications	Subject Device XTJF-Q160VF1	Predicate Device XTJF-160AF (K024033)
Field of View	100°	100°
Direction of View	Backward Sideviewing 5°	Backward Sideviewing 5°
Depth of Field	5~60mm	5~60mm
Optical System	color	color
Outer Diameter of Distal End	φ13.2mm	φ13.2mm
Outer Diameter of Insertion Tube	φ11.3mm	φ11.6mm
Angulation	UP : 120 DOWN : 90 RIGHT : 110° LEFT : 90°	UP : 120 DOWN : 90 RIGHT : 110° LEFT : 90°
Working Length	1240mm	1240mm
Inner Diameter of Instrument Channel	Φ4.2mm	Φ4.2mm

6. Conclusion

When compared to the predicate device, the XTJF-160AF 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2008

Olympus Medical Systems Corporation
% Ms. Laura Storm-Tyler
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
CENTER VALLEY PA 18034-0610

Re: K080403
Trade/Device Name: XTJF Q160VF1 DUODENOVIDEOSCOPE
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT
Dated: February 13, 2008
Received: February 14, 2008

Dear Ms. Storm-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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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 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): K080403
Device Name: XTJF-Q160VF1 DUODENOVIDEOSCOPE

Indications For Use:_

DUODENOVIDEOSCOPE XTJF-Q160VF1
This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the duodenum.

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 K080403