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K 101053

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510(k) SUMMARY

CF-Y0023-L/I COLONOVIDEOSCOPE

April 9, 2010

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

2 Device Identification

■ Device Trade Name:	CF-Y0023-L/I
■ Common Name:	COLONOVIDEOSCOPE
■ Regulation Number:	21 CFR 876.1500
■ Regulation Name:	Endoscope and accessories
■ Regulatory Class:	II
■ Classification Panel:	FDF: Colonoscope and Accessories, Flexible/Rigid NWB: Endoscope, Accessories, Narrow Band Spectrum
■ Product Code:	Gastroenterology and urology

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3 Predicate Device Information

- Device Name: XCF-H160AY2L
- Common Name: COLONOVIDEOSCOPE
- Manufacturer: Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No.: 9610595
- 510(k) No. K051645

4 Device Description

The CF-Y0023-L/I Colonovideoscope is a flexible video endoscope used for endoscopic diagnosis and treatment within the colon . The CF-Y0023-L/I Colonovideoscope is basically identical to the predicate device, Olympus XCF-H160AY2L Colonovideoscope, hereinafter referred to as XCF-H160AY2L in intended use, specifications, performance. The optical system of the CF-Y0023-L/I is a charge coupled device (CCD) based system, allowing endoscopic image display on a video monitor.

The major differences of the subject CF-Y0023-L/I Colonovideoscope from the predicate XCF-H160AY2L device are as follows:

-The number of objective lens and the width of the field of view for the subject and predicate devices differ. (CF-Y0023-L/I:140° (forward view) and 141- 233° (side view), XCF-H160AY2L: 170° (forward view))
-The shape of distal ends differ.
-The layout of the light guide lens differ.
-The number of air/water nozzles differ.(CF-Y0023-L/I:n=3, XCF-H160AY2L:n=1)

The new colonovideoscope CF-Y0023-L/I has both 140 degree forward view and 141-233 degree side view. Both forward view and side view are focused on one CCD, and the user can observe both 140 degree forward view and 141-233 degree side view at once.

5 Indications for Use

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.
Use the EVIS EXERA II COLONOVIDEOSCOPE CF-Y0023-L/I 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

The CF-Y0023-L/I is basically identical to the predicate device in intended use, and similar in specifications. There main difference are having a wider field view and a different shape of the distal end. Comparison between the subject and predicate devices is shown in Table 7.

Table 7. Comparison of Specifications

Specifications	Subject Device CF-Y0023-L/I	Predicate Device XCF-H160AY2L
Field of View	forward view : 140° side view : 141°~233°	170°
Depth of Field	forward view : 3.1～100mm side view : 0～60mm	2-100mm
Direction of View	forward view : 0° side view : 93.5°	forward viewing : 0°
Type of CCD	Color	Color
Outer Diameter of Distal End	φ13.9mm	φ13.9mm
Outer Diameter of Insertion Tube	φ12.8mm	φ12.8mm
Bending Section Angulation UP/DOWN	UP:180° DOWN:180°	UP: 180° DOWN:180°
Working Length	CF-Y0023-L=1680mm CF-Y0023-I=1330mm	1680mm
Inner Diameter of Instrument Channel	φ3.7mm	φ3.7mm

7 Conclusion

When compared to the predicate device, the CF-Y0023-L/I 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-G6(
Silver Spring, MD 20993-0002

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

JUL 14 2010

Re: K101053
Trade/Device Name: COLONOVIDEOSCOPE CF-Y0023-L/I
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: April 9, 2010
Received: April 15, 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.

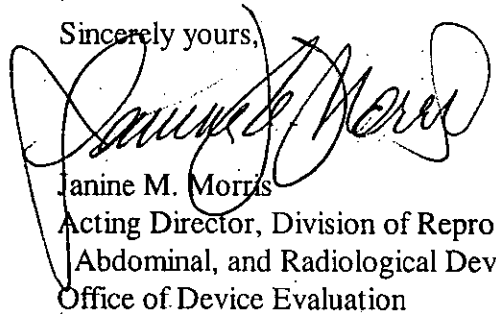
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K101053

Device Name: COLONOVIDEOSCOPE CF-Y0023-L/I

Indications For Use:

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Use the EVIS EXERA II COLONOVIDEOSCOPE CF-Y0023-L/I 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)

(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 K101053