OCT - 2 2003

K032177

Pg 1 of 3

SMDA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant: OLYMPUS OPT-ELECTRONICS CO., LTD.
(New Company Name: AIZU OLYMPUS CO., LTD)
Address: 500 Aza Muranishi Ooaza Niidera, Monden-machi
Aizuwakamatsu-shi Fukushima, Japan, 965-8520
Establishment Registration No.: 9610595

2. Submission Correspondent: Tina Steffanie-Oak
Title: Senior Regulatory Affairs Analyst
OLYMPUS AMERICA INC.
Address: Two Corporate Center Drive, Melville, NY 11747-3157
Telephone: 631-844-5477
Facsimile: 631-844-5416
E-mail address: Tina.Steffanie-Oak@olympus.com
Establishment Registration No.: 2429304

3. Initial Impoter: Olympus America Inc.
Address: Two Corporate Center Drive, Melville, NY 11747-3157
Establishment Registration No.: 2429304

B. DEVICE IDENTIFICATION

1. Common/Usual Name
GASTROINTESTINALVIDEOSCOPE / COLONOVIDEOSCOPE

2. Device Name
GASTROINTESTINALVIDEOSCOPE XGIF-Q140M, XGIF-2T140M
COLONOVIDEOSCOPE XCF-Q140ML/I, XPCF-160AML/I

3. Classification Name

CFR Number	Classification Name	Class	Product Code
876.1500	Endoscopes and accessories	II	78-FDS

K032177

Pg 2 of 3

C. IDENTIFICATION OF LEGALLY MARKETED DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

The following listed devices are considered as predicate devices in consideration of their characteristics, and the following table shows their regulatory histories.

Model	510(k)#	Manufacturer	Class	Product Code
GIF-Q140 EVIS-140 Series Scopes	#K954451	Olympus Optical Co., Ltd.	II	78-FDS
GIF-2T140 EVIS-140 Series Scopes	#K954451	Olympus Optical Co., Ltd.	II	78-FDS
CF-Q140L/I EVIS-140 Series Scopes	#K954451	Olympus Optical Co., Ltd.	II	78-FDS
PCF-140L/I EVIS-140 Series Scopes	#K954451	Olympus Optical Co., Ltd.	II	78-FDS
EVIS EXERA Colonovideoendoscopes	#K001241	Olympus Optical Co., Ltd.	II	78FDF

D. DEVICE DESCRIPTION

1. Summary

The subject devices, XGIF-Q140M, XGIF-2T140M, XCF-Q140ML/I, XPCF-160AML/I are basically identical to the predicate devices, GIF-Q140, GIF-2T140, CF-Q140L/I, PCF-140L/I except that the mechanical structure of variable stiffness* and Multi-bending function has been added.

*This feature has been added to XPCF-160AML/I only.

While XPCF-160AML/I has the mechanical structure of variable stiffness (Refer to Attachment 2, "Flexibility Adjustment Function") this feature is identical to those of another predicate device, the EVIS EXERA Colonovideoendoscopes (#K001241). The addition of the variable stiffness function does not require any new insertion method or technique.

The Multi-bending function has two independent bending sections in the insertion portion of the scope. This new function provides an easier approach in reaching the lesion and also a better view of the lesion from the front. Some lesions in the upper digestive tract were difficult to perform a perfect biopsy and endoscopy with the conventional forward-viewing gastroscope. (Refer to Appendix-3, "Clinical Literature"). The subject devices improve the approach to the lesion in the lower digestive tract compared with the predicate devices. We have evaluated the approach performance of the XPCF-160AMI compared to the predicate device using a colon model. (Refer to Attachment 1, "Comparison between approach performance of Predicate and Subject Device using a colon model").

In conclusion, the subject device is substantially equivalent to the predicate devices. A comparison table of the subject device and predicate devices is found in Attachment 1.

K032177

Pg 3 of 3

2. Design

XGIF-Q140M, XGIF-2T140M, XCF-Q140ML/I, XPCF-160AML/I has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1and IEC60601-2-18.

3. Materials

All the patient contacting materials used in this endoscope and ancillary equipment are identical materials that have been cleared in the past 510(k) submissions. And all materials have been confirmed with ISO 10993-1.

4. Intended Use of the device

GASTROINTESTINALVIDEOSCOPE XGIF-Q140M, XGIF-2T140M

This instrument has been designed to be used with the OLYMPUS Video System Center, Light Source, Documentation Equipment, Video Monitor, Electrosurgical unit, Endo-Therapy 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).

COLONOVIDEOSCOPE XCF-Q140ML/I, XPCF-160AML/I

This instrument has been designed to be used with the OLYMPUS Video System Center, Light Source, Documentation Equipment, Video Monitor, Electrosurgical unit, Endo-Therapy Accessories such as a Biopsy Forceps and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, and sigmoid colon, colon, and ileocecal valve).

5. Summary including conclusion drawn form Non-clinical Tests

When compared to the preamendment/predicate devices, XGIF-Q140M, XGIF-2T140M, XCF-Q140ML/I, XPCF-160AML/I does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety and effectiveness. Therefore clinical data is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

OLYMPUS OPT-ELECTRONICS CO., LTD./AIZU OLYMPUS CO., LTD.
c/o Ms. Tina Steffanie-Oak
Senior Regulatory Affairs Analyst
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K032177
Trade/Device Name: Gastrointestinal Videoscope, XGIF-Q140M, XGIF-2T140M and Colonovideoscope, XCF-Q140ML/I, XPCF-160AML/I
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FDS and FDF
Dated: July 11, 2003
Received: July 16, 2003

Dear Ms. Steffanie-Oak:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K032177

Pg 1 of 1

510(k) Number(if known): K032177

Device Name: GASTROINTESTINAL VIDEOSCOPE XGIF-Q140M, XGIF-2T140M
COLONOVIDEOSCOPE XCF-Q140ML/I, XPCF-160AML/I

Indications for Use:

GASTROINTESTINAL VIDEOSCOPE XGIF-Q140M, XGIF-2T140M

This instrument has been designed to be used with the OLYMPUS Video System Center, Light Source, Documentation Equipment, Video Monitor, Electrosurgical unit, Endo-Therapy 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).

COLONOVIDEOSCOPE XCF-Q140ML/I, XPCF-160AML/I

This instrument has been designed to be used with the OLYMPUS Video System Center, Light Source, Documentation Equipment, Video Monitor, Electrosurgical unit, Endo-Therapy Accessories such as a Biopsy Forceps and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, and sigmoid colon, colon, and ileocecal valve).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032177