K033225

SMDA 510(k) SUMMARY 10-16-03

August 22, 2003
Revised March 19, 2007

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

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Japan
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2. Submission Correspondent

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3. Official Correspondent

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B. DEVICE IDENTIFICATION

1. Common/Usual Name

Bronchoscope, its accessories and ancillary equipment

2. Device Name

EVIS EXERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE XP160F, its accessories and ancillary equipment

3. Classification Name

CFR Number	Classification Name	Class	Product Code
874. 4680	Bronchoscopes (flexible and rigid) and accessories	II	EOQ

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

Model	510(k)#	Manufacturer	Class	Product Code
OES Bronchofiberscope Olympus BF type XP40	#K023984	Olympus Optical Co., Ltd.	II	EOQ
EVIS EXERA Bronchovideoscope Olympus BF type 160	#K023984	Olympus Optical Co., Ltd.	II	EOQ
OES Video Converter Olympus OVC-200	#K931154	Olympus Optical Co., Ltd.	II	EOQ

D. DEVICE DESCRIPTION

1. Summary

The subject device, EVIS EXERA Bronchofibervideoscope Olympus BF type XP160F is basically identical to the predicate device, OES Bronchofiberscope Olympus BF type XP40 (BF-XP40) except that the subject device is equipped with the CCD in the control section. The fiber bundle in the insertion tube transmits images to the CCD in the control section, and the CCD changes them to video signals. In principle, the subject device is equivalent to the combination of the BF-XP40 and the OES Video Converter Olympus OVC-200. The CCD equipped with the subject device is identical to that of the EVIS EXERA Bronchovideoscope Olympus BF type 160 (BF-160). By combining the CCD in the scope's control section, the insertion tube diameter of the subject device is narrower than that of the BF-160. In comparison with the BF-XP40, the performance of operation is improved because it is not necessary to attach the video converter.

2. Design

The EVIS EXERA Bronchofibervideoscope Olympus BF type XP160F has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1, IEC60601-1-2 and IEC60601-2-18.

3. Materials

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

4. Intended Use of the device

This instrument has been designed to be used with the 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 airways and tracheobronchial tree.

5. Summary including conclusion drawn from Non-clinical Tests

When compared to the predicate device, the BF type XP160F does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect safety and effectiveness. Therefore clinical data is not necessary for evaluation of safety and efficacy.

6. Comparisons between the subject device and predicate devices

The intended use of the subject device, the BF-XP160F, is substantially identical to that of the predicate devices, the BF-XP40 and BF-160. The specification of the subject device is identical to that of the BF-XP40, except that the subject device is equipped with the CCD in the control section. The CCD used for the subject device is completely same as that used for the other predicate device, the BF-160.

CHARACTERISTICS	Subject device	Predicate device (#K023984)	
	BF-XP160F	**BF-XP40**	**BF-160**
Intended Use	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 airways and tracheobronchial tree.	Designed to be used with an Olympus light source, documentation equipment, display monitor, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the airways and tracheobronchial tree.	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 airways and tracheobronchial tree.
Optical Characteristics Field of view Depth of Field Direction of view	 90° 2mm~50mm 0° Forward Viewing	 90° 2mm~50mm 0° Forward Viewing	 120° 3mm~100mm 0° Forward Viewing
Outer Diameter of Distal End	2.8mm	2.8mm	5.3mm
Outer Diameter of Insertion Tube	2.8mm	2.8mm	5.3mm
Angulation UP/DOWN	180° /130°	180° /130°	180° /130°
Working Length-Insertion Tube	600mm	600mm	600mm
Instrument Channel-I.D.	1.2mm	1.2mm	2.0mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Olympus Optical Co., Ltd.
c/o Ned Devine
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K033225
Trade/Device Name: EVIS EXERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE XP160F, its accessories and ancillary equipment
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: August 22, 2003
Received: October 6, 2003

Dear Mr. Devine:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K033225

Device Name: EVIS EXERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE XP160F, its accessories and ancillary equipment

Indications for Use:

The EVIS Bronchofibervideoscope Olympus BF type XP160F 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 airways and tracheobronchial tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K033225