K040940

APR 1 9 2004

510(k) SUMMARY

Bronchovideoscope Olympus XBF-D160HM

1. General Information

Date Prepared	February 20, 2004
Applicant	Olympus Corporation (Former name: Olympus Optical Co., Ltd.) 34-3 Hirai Hinode-machi, Nishitama-gun, Tokyo, 190-0182, Japan Establishment Registration No.: 3003637092
Submission Correspondent	Shiho Otsuki Olympus Corporation (Former name: Olympus Optical Co., Ltd.) 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507, Japan Phone: +81-426-42-2891 Fax: +81-426-42-2291 Email: sh_otsuki@ot.olympus.co.jp Establishment Registration No.: 8010047
Official Correspondent	Tina Steffanie-Oak Associate Manager, Regulatory Affairs/Clinical Monitor Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-3157, USA Phone: 631-844-5477 FAX: 631-844-5416 Email: Tina.Steffanie-Oak@olympus.com Establishment Registration No.: 2429304

2. Device Identification

Trade Name:	Bronchovideoscope Olympus XBF-D160HM
Common Name:	Bronchoscope
Regulation Name:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	21 CFR 874.4680
Class:	2
Product Code:	77 EOQ

3. Predicate Device

Predicate Device Name:	EVIS EXERA Bronchovideoscope Olympus BF type 160
Manufacturer:	Olympus Optical Co., Ltd.
510(k) Number:	K023984

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4. Device Description

The subject device, Bronchovideoscope Olympus XBF-D160HM, is basically identical to the predicate device, EVIS EXERA Bronchovideoscope Olympus BF type 160, except that the subject device is equipped with an optical system for high magnification observation in addition to an optical system for normal observation.
When compared to the predicate device, this high magnification bronchoscope enables more detailed observation of the target area. For example, a run of the capillary blood vessel in the bronchial mucosa can be observed, which is not observable with the predicate device.

5. Intended Use

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 airways and tracheobronchial tree.

6. Comparison of Technological Characteristics

The XBF-D160HM is identical to the BF-160 in intended use, and similar in specifications except for the optical system. Comparison between the subject device and predicate device is in Table 4.

Table 4 □Comparison between the subject device and predicate device

Specifications	Subject Device XBF-D160HM	Predicate Device BF-160 (K023984)
Distal End Outer Diameter	□5.9mm	□5.3mm
Insertion Tube Outer Diameter	□5.7mm	□5.3mm
Inner Channel Diameter	□2.0mm	□2.0mm
Optical system	High magnification observation and Normal observation	Normal observation

7. Materials

All the patient contact materials used in the subject device are identical to those used in the devices cleared in the past 510(k) submissions.

8. Conclusion

When compared to the predicate device, the XBF-D160HM does not incorporate any significant changes in 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

APR 1 9 2004

Olympus Corporation
c/o Tina Steffanie-Oak
Associate Manager, Regulatory Affaire/Clinical Monitor
Two Corporate Center Drive
Melville, NY 11747

Re: K040940
Trade/Device Name: Bronchovideoscope Olympus XBF-D160HM
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories)
Regulatory Class: Class II
Product Code: EOQ
Dated: February 20, 2004
Received: April 12, 2004

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 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

Indications for Use

510(k) Number (if known):

Device Name: Bronchovideoscope Olympus XBF-D160HM

Indications For Use:

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 airways and tracheobronchial tree.

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)

Karen H Soltis

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

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