K023984

JAN 31 2003

Revised 1/27/03

SMDA 510(k) SUMMARY

Olympus Bronchoscopes BF-40, 240 and 160 series

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 34-3 Hirai Hinide-Machi, Nishitama-Gun , Tokyo 190-00182, Japan
Registration No.:	3003637092
Address, Phone and Fax Numbers: Of R&D Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81- 426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Trade Name, Common Name, Classification Name and Predicate Devices

<Olympus Bronchoscopes BF-40 series>

Trade Name:	Olympus Bronchoscopes BF-40 series
Common Name:	Bronchoscope
Classification:	21 CFR 874.4680 Bronchoscopes (flexible or rigid) and accessories, Class II
*Predicate Device:	BF-N20(#K910423)

<Olympus Bronchoscopes BF-240, 160 series>

Trade Name:	Olympus Bronchoscopes BF-240, 160 series
Common Name:	Bronchoscope
Classification:	21 CFR 874.4680 Bronchoscopes (flexible or rigid) and accessories, Class II

* Predicate Device: BF-240, BF-P240,BF-1T240 (#K963033)

*The difference between the predicate devices and subjects devices is only a change in material of the Biopsy Port. The change in material would not effect safety and effectiveness of the device.

D. Description of the Device(s)

< BF-40 Series>
These instruments have been designed to be used with an Olympus Light Source, documentation equipment, display monitor, Endo-Therapy Accessories and other ancillary equipment for endoscopic diagnostic and treatment within the airways and tracheobronchial tree.

<BF-240 Series>
This instrument has been designed to be used with an Olympus Video System Center, Light Source, Documentation Equipment, Display monitor, Endo-Therapy Accessories, Electrosurgical Unit, and other ancillary equipment for endoscopic diagnosis and treatment within the airways and tracheobronchial tree.

<BF-160 Series>
These instrument have 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.

E. Intended Use of the Device(s)

< BF-40 Series>
These instruments have been designed to be used with an Olympus Light Source, documentation equipment, display monitor, Endo-Therapy Accessories and other ancillary equipment for endoscopic diagnostic and treatment within the airways and tracheobronchial tree.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2003

Olympus Optical Co., LTD
c/o Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

Re: K023984
Trade/Device Name: Olympus Bronchoscopes BF-40, 240, 160
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscopes (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: November 26, 2002
Received: December 2, 2002

Dear Ms. Storms-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 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 STATEMENT

510(k) Number(if known): ~~Not assigned yet.~~ K023984

Device Name: Olympus Bronchoscopes BF-40, 240, 160

Indications for Use:

< BF-40 Series>

These instruments have been designed to be used with an Olympus Light Source, documentation equipment, display monitor, Endo-Therapy Accessories and other ancillary equipment for endoscopic diagnostic and treatment within the airways and tracheobronchial tree.

<BF-240 Series>

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<BF-160 Series>

These instrument have 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 ✓ 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 K023984