K022446

MAR 2 8 2003

SMDA 510(k) SUMMARY

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

Name & Address of manufacturer:	Olympus Opto-Electronics Co., Ltd. Aomori Plant 248-1 Okkonoki 2-chome Kuroishi-shi Aomori, Japan, 036-0367
Registration No.:	9614641
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 426-42-2891 FAX 426-42-2291

B. Name of Contact Person

Name:	Ms. 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) 844-5554

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

Trade Name:	Mucus Collection Probe BC-401C, BC-402C,
Common Name:	Bronchoscope accessory
Classification:	Bronchoscope and accessories 21 CFR 874.4680
Predicate Device:	BC-14C/15C/16C Cytology Brush, manufactured by Olympus (K931154 EVIS-200 System Olympus Videobronchoscope & Accessories)

COMPARISON TABLE

		Subject Devices: BC-401C/402C	Predicate Device: BC-14C/15C/16C (# K931154)
Labeling	Intended Use	The subject devices are designed to be used with an Olympus bronchoscope for the collection of bronchial secretions in the bracheobronchial tree. Bronchial fluids absorbed onto the fiber tip of the collection probe are subsequently analyzed for biochemical constituents.	This instrument has been designed to be used with Olympus endoscopes to collect tissue specimens in the Tracheo-bronchial Tree.
	Operation	Bronchoscopic Microsampling: Insert the instrument in the endoscope with the fiber rod retracted into the tube. Advance the distal end of the insertion portion toward target area. Extend the fiber rod from the tube, and contact the target area to collect bronchial secretions.	Insert the instrument into the endoscope with the brush retracted in the tube. Advance the distal end of the insertion portion toward target area. Extend the brush from the tube, and brush the target area to collect tissue specimen.
Design	Maximum diameter	1.8mm, 2.5mm	1.8mm
	Insertion portion diameter	1.7mm, 2.4mm	1.7mm
	Brush diameter	1mm	2.4mm, 3mm
	Brush length	5mm	6mm, 10mm
	Fiber rod diameter	1.1mm, 1.9mm	
	Fiber rod length	30mm, 20mm	
	Working length	1050mm	1050mm, 1050mm
	Applicable endoscope channel size	2mm or more	2mm or more

D. Description of the Device(s)

Mucus Collection Probes, BC-401C and BC-402C, have been designed to be used with an Olympus endoscope to collect bronchial secretions in the tracheobronchial tree. Bronchial fluids absorbed onto the fiber tip of the collection probe are subsequently analyzed for biochemical constituents. Single use.

E. Intended Use of the Device(s)

The subject devices are designed to be used with an Olympus bronchoscope for the collection of bronchial secretions in the brocheobronchial tree. Bronchial fluids absorbed onto the fiber tip of the collection probe are subsequently analyzed for biochemical constituents.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the subject device does not add any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

Aomori Olympus Co., Ltd.
c/o Laura Storms-Tyler
Olympus America, Inc.
2 Corporate Center Drive
Melville, NY 11747-3157

Re: K022446
Trade/Device Name: Olympus Mucous Collection Probe BC-401C, BC-402C
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 23, 2002
Received: March 13, 2003

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

OLYMPUS

Indications for Use Statement

510(k) Number(if known): Not assigned yet. K022446
Device Name: Mucus Collection Probe

Indications for Use :

The subject devices are designed to be used with an Olympus bronchoscope for the collection of bronchial secretions in the tracheobronchial tree. Bronchial fluids absorbed onto the fiber tip of the collection probe are subsequently analyzed for biochemical constituents.

(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
(Prescription 21 CFR 801.109)

(Optional Format 1-2-96)

Karen F Baker

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

510(k) Number K022446

Prescription Use ✓
(Per 21 CFR 801.109)