~~K012703~~
K012073

AUG 1 0 2001

SMDA 510(k) SUMMARY

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

1. Manufacturer of the subject device

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishi-Shinjuku, Shinjyuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 426-42-5177 FAX 426-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler 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:	Spray Catheter PW-6C-1, Injection Valve MAJ-929
Common Name:	Catheter / Valve
Classification:	Bronchoscope and accessories 21 CFR 874.4680
Predicate Device:	Cannula PR-2 (K931154 EVIS-200 System Videobronchoscope & Accessories)

D. Description of the Device(s)

Spray Catheter PW-6C-1 has been designed to be used with an Olympus endoscope to perform washing, and spraying of contrast media or medicine (e.g. anesthetics) within the airway, including the tracheobronchial tree. PW-6C-1 is used in combination with Injection Valve MAJ-929 to spray fluid continuously. Both PW-6C-1 and MAJ-929 are non-sterile, reusable.

E. Intended Use of the Device(s)

This instrument has been designed to be used with an Olympus endoscope for washing, and spraying contrast media or medicine (e.g. anesthetics) within the airway, including tracheobronchial tree.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the subject device does not incorporate 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

FEB 2 9 2002

The Olympus Optical Co., Ltd.
c/o Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
2 Corporate Center Dr.
Melville, NY 11747-3157

Re: K012073
Trade/Device Name: Olympus Bronchoscopic Spray Catheter PW-6C-1
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 28, 2001
Received: July 2, 2001

Dear Ms. Tyler:

This letter corrects our substantially equivalent letter of August 10, 2001 regarding the Olympus Bronchoscopic Spray Catheter PW-6C-1. Our original letter incorrectly stated the 510(k) number as K012703. This letter corrects that error.

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). 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

David M. Whipple

for 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

510(k) Number(if known): K012073

Device Name: SPRAY CATHETER

Indications for Use:

This instrument has been designed to be used with an Olympus Bronchoscope for washing, and spraying contrast media or medicine (e.g. anesthetics) within the airway, including the tracheobronchial tree.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012073

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ JS OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optoinal Format 1-2-96)