K981543

JUN - 8 1998

SMDA 510(k) Summary
Olympus Tracheal Intubation Fiberscope LF-TP and LF-DP

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

A. Submitter's Name, Address, Phone and Fax Number:

Olympus Optical Co., Ltd.
22-2 Nishi-Shinjuku
Shinjuku-ku, Tokyo 163-8610
Japan

B. Contact Person's Name, Address, Phone and Fax Numbers

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Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, NY 11747-3157
Telephone: (516) 844-5688
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C. Trade Name, Common Name and Classification Name

Trade Name:	Olympus LF-TP and LF-DP Tracheal Intubation Fiberscope, accessories and ancillary equipment
Common Name:	Portable Bronchofiberscope, accessories and ancillary equipment
Classification:	Bronchoscope and accessories Class II, 21 CFR 874.4680

D. Legally Marketed Devices which we Claim Substantial Equivalence

Olympus LF-1 Intubation Scope	K850978
Olympus BF-240 Bronchovideoscope	K963033
Olympus BF-200 Bronchovideoscope	K931154
Olympus BF-P200 Bronchovideoscope	K931154
Olympus Winter & Ibe A5255A Rigid Endoscope	K923982
Olympus A3093 Light Guide Cable, 3.5 mm plug type	K944072

E. Description of the Device

The Olympus LF-TP and LF-DP Tracheal Intubation Fiberscopes and it's accessories are specifically designed to be used with a Suction Pump and other ancillary equipment for airway management.

F. Intended Use of the Device

The Olympus LF-TP and LF-DP Tracheal Intubation Fiberscopes are specifically designed for airway management which includes endoscopic observation to assess airway anatomy, endotracheal/endobronchial intubation, and management.

The difference between the LF-TP and LF-DP fiberscopes are as follows:

- Distal end outer diameter
- Insertion tube outer diameter
- Channel inner diameter
- Angulation range

G. Summary of the Technological Characteristics of the Device compared to the Predicate Device(s)

Except for the combined use with the Miniature Light Source and some modifications for the improvement of performance, other characteristics of the Olympus LF-TP and LF-DP Tracheal Intubation Fiberscopes are identical to the predicate Olympus LF-1 Intubation Scope.

H. Summary including a Brief Discussion of Non-Clinical Tests and How their Results support Determination of SE

Olympus LF-TP and LF-DP Tracheal Intubation Fiberscopes are designed, manufactured, and tested in compliance with the requirements of the voluntary safety standard, IEC 60601-1.

I. Summary including Conclusions drawn from Non-Clinical Tests

When compared to the predicate devices, Olympus LF-TP and LF-DP Tracheal Intubation Fiberscopes do not incorporate any significant change in intended use, method of operation, material, and design that could affect device safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 1998

Laura Storms-Taylor
Director, Regulatory Affairs
Olympus Optical Co., Ltd.
22-2 Nishi-Shinjuku, 1-Chome
Shinjuku-ku, Tokyo 163-8610
Japan

Re: K981543
Olympus LF-TP and LF-DP Tracheal Intubation Fiberscopes, accessories and ancillary equipment
Dated: April 28, 1998
Received: April 30, 1998
Regulatory class: II
21 CFR 874.4680/Procode: 77 EOQ

Dear Ms. Storms-Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): Not assigned yet K981543

Device Name: **Olympus LF-TP and LF-DP Tracheal Intubation Fiberscope, accessories and ancillary equipment.**

Indications for Use:

Olympus LF-TP and LF-DP Tracheal Intubation Fiberscope, accessories and ancillary equipment are intended for airway management which includes endoscopic observation to assess airway anatomy, endotracheal/endobronchial intubation, and management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21CFR 801.109) OR Over-the Counter Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981543