DEC 2 6 2001

K013591

510(k) SUMMARY

XENF-TP Rhino-Laryngo fiberscope, its accessories and ancillary equipment

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

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	8010047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

2 Name of Contact Person

Name :	Ms. Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157
Address, Phone and Fax :	TEL (631)844-5688 FAX (631) 844-5416

B. Device Name, Common Name

1. Device Name :	XENF-TP Rhino-Laryngofiberscope, its accessories and ancillary equipment
2. Common/Usual Name :	Fiber Scope for Rhino-Laryng Fiberscope
3. Classification Name :	21CFR 876.1500 21CFR 868.5530 21CFR 874.4760

C. Predicate Devices:

Model	Device Description & 510(k)#/ Date Cleared	Manufacturer
Pentax Naso-Pharyngo-Laryngosocope FNL-15P2/15RP2	#K921707 07/01/1992	Pentax Precision Instrument Corp
Laparoscope, Hand Instruments	#K950103 03/06/1995	Olympus America,Inc.
LF-TP/DP	#K981543 08/06/1998	Olympus Optical Co.,

D. Summary Description of the Device

1. Summary

This subject device "XENF-TP Rhino-Laryngofiberscope" is an endoscope used for treatment and observation within the nasal and nasopharyngeal lumen. This endoscpe can be used with two types of light sources, detachable with an reusable battery powered and light cable source. This device is equipped instrument channel, so this device is suitable for treatment within the nasal and nasopharyngeal lumen using recommended ancillary equipment.

2. Design

"XENF-TP Rhino-Laryngofiberscope" has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC 60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-2-18.

3. Materials

There are no new patient-contacting materials. All of patient contact materials are cleared by previous 510(k) submissions such as LF-TP/DP.

E. Intended Use of the device

This instruments has been designed to be used with an Olympus Light Source or an Olympus Miniature Light Source, documentation equipment, display monitor, Endo-Therapy accessories and other ancillary equipment for endoscpic diagnosis and treatment within the nasal and nasopharyngeal lumen. Do not use this instrument for any purpose other than its intended use.

F. Technological Characteristics

This endoscope does not have special technological characteristics compared to the predicate device.

G. Reason for not requiring clinical data

Compared to the predicate devices, "XENF-TP Rhino-Laryngofiberscope" does not incorporate any significant change for safety and efficacy to the predicate device. Treatment and observation within nasal and nasopharyngeal lumen have been done widely, and established its 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

DEC 26 2001

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

Re: K013591
Trade/Device Name: XENF-TP Rhino-Laryngofiberscope, its accessories and ancillary equipment
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope
Regulatory Class: Class II
Product Code: EOB
Dated: October 29, 2001
Received: October 30, 2001

Dear Ms. Storms-Tyler:

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 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

OLYMPUS

Indication for Use Statement

510(k) Number(if known): ~~Not assigned yet.~~ K013591

Device Name: XENF-TP Rhino-Laryngofiberscope, its accessories and ancillary equipment.

Indications for Use:

Fiberscope:

This instrument has been designed to be used with an Olympus Light Source or an Olympus Miniature Light Source, documentation equipment, display monitor, Endo-Therapy Accessories and other ancillary equipment for endoscopic diagnosis and treatment within the nasal and nasopharyngeal lumen.

Miniature Light Source:

MAJ-524 is a detachable battery powered Miniature Light Source, which has been designed to be used with the XENF-TP.

FB-56D-1

These instruments have been designed to be used with an Olympus endoscope to collect tissue within the nasal and nasopharyngeal lumen.

FG-53SX-1

These instruments has been designed to be used with an Olympus endoscope to retrieve foreign bodies, calculi or resected tissue from the nasal and nasopharyngeal lumen.

BC-201C/ BC-8C/BC-10C

These instruments has been designed to be used with an Olympus endoscope to collect tissue specimens within the nasal and nasopharyngeal lumen.

NM-101C-0427 / NM-201L-0423 / NM-201L-0525

These instruments has been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection within the nasal and nasopharyngeal lumen.

PW-6C-1/MAJ-929

These instruments has been designed to be used with an Olympus endoscope for spraying medications in the nasal and nasopharyngeal lumen.

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

510(k) Number K013591

(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)