K082720

OLYMPUS

NOV - 5 2008

510(k) SUMMARY

TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004 and LF-Y0005

September 8, 2008

1 General Information

- Applicant:
  OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent:
  Stacy Abbatiello Kluesner, RAC
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5405
  Fax: 484-896-7128
  Email:stacy.kluesner@olympus.com
  Establishment Registration No: 2429304

- Manufacturer:
  Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No: 9610595

2 Device Identification

- Device Trade Name:
  TRACHEAL INTUBATION FIBERVIDEOSCOPE
  LF-Y0004 and LF-Y0005
- Common Name:
  TRACHEAL INTUBATION FIBERVIDEOSCOPE
- Regulation Number:
  21 CFR 874.4680
- Regulation Name:
  Bronchoscope (flexible or rigid) and accessories
- Regulatory Class:
  II
- Classification Panel:
  Ear Nose & Throat
- Product Code:
  EOQ - Bronchoscope (Flexible Or Rigid)

: 00329

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3 Predicate Device Information

The following table shows the primary components of the subject devices and the devices to which we claim substantial equivalence (predicate devices).

Table 14-1. Primary Components & Predicate Devices

Subject Devices (Part of this submission)	Predicate Devices	PD's 510(k) No.
TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004	Olympus LF-DP Tracheal Intubation Fiberscope	K981543
	EVIS EXERA BRONCHOFIBERVIDEO SCOPE OLYPUS BF TYPE XP160F	K033225
TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0005	Olympus Bronchoscope BF-XT40	K023984

4 Device Description

The TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004 and LF-Y0005 are all-in-one cordless endoscopes with great portability which include light source, video processor, and video monitor functions.

The new endoscopes are basically identical to each predicate device shown in Table 14-1 in intended use, and similar in specifications, performance and materials.

5 Indications for Use

These instruments have been designed to be used with a Suction Pump and EndoTherapy accessories and other ancillary equipment for airway management, which includes endoscopic treatment, diagnosis, and observation to access airway anatomy, endotracheal/endobronchial intubation and management.

6 Comparison of Technological Characteristics

The TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004 and LF-Y0005 are basically identical to the predicate device in intended use, and similar in specifications except for the all-in-one unit, outer diameter, and optical system. Comparison between the subject and predicate devices is shown in Table 14-2.

Table 14-2. Comparison of Specifications

Subject Devices : TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004 and LF-Y0005

Predicate Devices : TRACHEAL INTUBATION FIBERSCOPE OLYMPUS LF-DP (K981543)
EVIS EXERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE XP160F (K033225)
OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE XT40 (K023984)

Specifications	Subject Device LF-Y0004	Subject Device LF-Y0005	Predicate Device LF-DP	Predicate Device BF-XP160F	Predicate Device BF-XT40
Field of View	90°	90°	90°	90°	120°
Depth of Field	4-50mm	3-50mm	3-50mm	2-50mm	3-50mm
Direction of View	0° (Forward viewing)	0° (Forward viewing)	0° (Forward viewing)	0°(Forward viewing)	0°(Forward viewing)
Outer Diameter of Distal End	φ3.9mm	φ5.1mm	φ3.1mm	φ2.8mm	φ6.1mm
Outer Diameter of Insertion Tube	φ4.1mm	φ5.2mm	φ3.1mm	φ2.8mm	φ6.2mm
Angulation UP/DOWN	UP : 120° DOWN : 120°	UP : 180° DOWN : 130°	UP : 120° DOWN : 120°	UP : 180° DOWN : 130°	UP : 180° DOWN : 130°
Working Length	600mm	600mm	600mm	600mm	550mm
Source of examination light	These are built-in functions of the endoscope.	These are built-in functions of the endoscope.	External Light Source Unit	External Light Source Unit	External Light Source Unit
Video processor			External Video System Center Unit (when connected via Video Converter Unit)	External Video System Center Unit	External Video System Center Unit (when connected via Video Converter Unit)
Monitor			External Video Monitor Unit	External Video Monitor Unit	External Video Monitor Unit

7 Conclusion

When compared to the predicate device, the TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004 and LF-Y0005 do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Medical System Corporation
c/o Stacy Abbatiello Kluesner
Olympus America, Inc
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034

NOV - 5 2008

Re: K082720
Trade/Device Name: Tracheal Intubation Fiberscope LF-Y0004 and LF-Y0005
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOQ
Dated: September 16, 2008
Received: September 23, 2008

Dear Ms. Kluesner:

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.

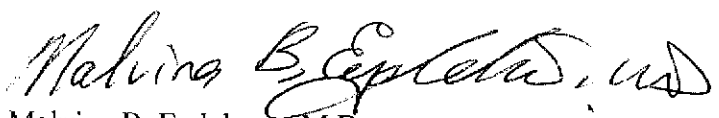
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082720

Indications for Use

510(k) Number (if known):

Device Name: TRACHEAL INTUBATION FIBERVIDEOSCOPE LF-Y0004, LF-Y0005

Indications For Use:

These instruments have been designed to be used with a Suction Pump and EndoTherapy accessories and other ancillary equipment for airway management, which includes endoscopic treatment, diagnosis, and observation to access airway anatomy, endotracheal/endobronchial intubation and management.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082720

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