K060243

JUN 23 2006

January 23 , 2006

SMDA 510(k) SUMMARY
"Olympus Guide Sheath, XBO1-836-13 "

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant :

Olympus Medical Systems Corporation
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Registration number :8010047

2. Official Correspondent :

Laura Storm-Tyler
Executive Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-9058, USA
TEL 631-844-5688
FAX 631-844-5554
Registration Number :2429304

3. Manufacturer :

Aomori Olympus Co., Ltd.
2-248-1 Okkonoki Kuroishi-shi, Aomori-ken,
036-0357, Japan
Registration Number : 9614641

B. DEVICE IDENTIFICATION

1. Common/Usual Name : Bronchoscope accessory

2. Device Name : Olympus Guide Sheath, XBO1-836-13

3. Classification Name : 874.4680, class II , EOQ

C. PREDICATE DEVICES

Device Name	510(k) #	Manufacturer	Class	Product Code
Cytology Brush: BC-14/15/16C (EVIS 200 System)	#K931154	Olympus Corporation.	II	EOQ

D. SUMMARY DESCRIPTION OF THE DEVICE

1. Summary

Olympus Medical Systems Corp., intends to introduce the Guide Sheath for use in the respiratory organs. This Guide Sheath,XBO1-836-13 has been designed to be used with Olympus bronchoscopes with 2.8 mm instrument channel, accessories and ultrasonic probe unit for performing diagnostic and therapeutic procedures. The Guide Sheath allows physicians to advance the endo-therapy accessories or guide the ultrasonic probe precisely to the targeted lesions repeatedly.

2. Materials

The patient contacting materials used as components of the Guide Sheath are identical to legally Marketed Olympus products.

E. SUMMARY

In summary, the Guide Sheath, XBO1-836-13 is basically identical to the predicate device in performance, materials and specifications. The subject device differs from the predicate device relative to the intended use.

F. INTENDED USE OF THE DEVICE

This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the targeted area within the respiratory organs.

G. TECHNOLOGICAL CHARACTERISTICS

This Guide Sheath, XBO1-836-13 consists of tube sheath and piece of flouro tip, which shows the distal end position when X-ray was monitored. The following is the specification of the Guide Sheath;

Specifications	Dimension (m)
Outer Diameter	2.7
Inner Diameter	2.1
Sheath Length	900
Channel Size (Minimum ϕ)	2.8
Fluoro Tip for X-ray monitor	Provided

H. CLINICAL DATA

Olympus sponsored prospective clinical evaluation of the subject device which support the safe and effective use of the subject device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

Olympus Medical Systems Corporation
c/o Ms. Laura Storm-Tyler
Two Corporate Center Dr.
Melville, NY 11747-9058

Re: K060243
Trade/Device Name: Olympus Guide Sheath, XBO1-836-13
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories (flexible or rigid)
Regulation Class: II
Product Code: EOQ
Dated: May 30, 2006
Received: May 31, 2006

Dear Ms. Storm-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 (240) 276-0115. 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 (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

Indications for Use Statement

510(k) Number (if known) : K060243

Device Name: Olympus Guide Sheath, XBO1-836-13

Indications for Use :

This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the target area within the respiratory organs.

(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_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K060243