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June .27. 2005

SMDA 510(k) SUMMARY

"Olympus Choledochoscope Model XCHF- BP160F"

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 Corp.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
Registration number : 8010047

2. Official Correspondent :

Laura Storms-Tyler
Executive Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-9058, USA
Telephone : 631-844-5688
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E-mail : Laura Storms-Tyler@olympus.com
Registration number : 2429304

3. Manufacturer :

Aizu Olympus Co., Ltd.
500 Aza Muranishi Ooaza, Niidera, Monden-machi,
Aizuwakamatsu-shi, Fukushima, 965-8520 Japan
Registration number : 9610595

B. Device Identification

1. Common/Usual Name : Choledochoscope

2. Device Name : OLYMPUS CHOLEDOCHOSCOPE Model XCHF- BP160F

3. Classification Name

CFR Number	Classification Name	Class	Product Code
876.1500	Choledochoscope flexible or rigid	II	78 FBN

C. Identification of the predicate or legally marketed device(s)

The following listed devices are the predicate medical devices;

Model	510(k)#	Manufacturer	Class	P-code
OES Transduodenal Choledocho-scope, CHF type B20	#K904799	Olympus Optical Co., Ltd	II	KOG
EVIS EXERA Bronchofiber-videoscope BF type XP160F	#k033225	Olympus Optical Co., Ltd	II	EOQ

D. General Description

This instrument has been designed to be used with Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories and other ancillary equipment for endoscopy and endoendoscopic surgery within the biliary tract and pancreatic duct in conjunction with the TJF-duodenoscope.

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E. Device Description

The XCHF-BP160F Choledochoscope is basically identical to the predicate device, OES Transduodenal Choledochofiberscope CHF type B20 except that the subject device is equipped with the high resolution CCD in the control section, in addition to the fiber bundle in the insertion tube. Images are transmitted through the fiber bundle and converted by the CCD in the control section to video signals.This is a hybrid technology and substantially equivalent to another Olympus predicate device, Olympus bronchoscope, model BF type XP160F(K033225).

The XCHF-BP160F Choledochoscope is used in conjunction with the TJF-duodenoscope with an instrument channel with a minimum diameter of ϕ 4.2mm, such as Olympus TJF type 100, TJF type 140, TJF type 160F/VF and TJF type M20 duodenoscopes. The XCHF-BP160F Choledochoscope is safety and effectively delivered through the upper gastrointestinal (GI tract to the Papilla of Vater) by traveling through the instrument channel of the TJF-duodenoscopes. At this point, XCHF-BP160F Choledochoscope can directly observe the billiary tract or pancreatic duct.

The technique of using a TJF-duodenoscope to introduce a Choledochoscope, such as the subject device, into the common bile duct is similar to the method commonly used to introduce catheters, stents and other accessories into the biliary tract and pancreatic duct.

F. Summary

In summary, the new Choledochoscope, XCHF-BP160F is basically identical to the predicate device in intended use, similar in specification, performance and materials. The subject device differs in that the indication for use have been expanded to include observation of the pancreatic duct, and the high resolution CCD is installed in the control section.

G. Design

The Choledochoscope XCHF-BP160F has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1:1998+ Amendment 1:1991+Amendment 2:1995, IEC 60601-1-1:2000 and IEC60601-2-18: 1996+ Amendment1:2000.

H. Intended use of the device

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and ancillary equipment or endoscopy and endoscopic surgery within the biliary tract and pancreatic duct in conjunction with DUODENOSCOPE with an instrument channel with a minimum diameter of ϕ 4.2mm.

I. Comparison Technological Characteristics

Comparison between the subject device and predicate device is as follow:

Items	XCHF-BP160F (Subject Device)	CHF type B20 (Predicate Device) K904799	BF type XP160F (Predicate Device) K033225
Imaging system	CCD	Optical fiber bundle	CCD
Insertion diameter	ϕ 2.9 – 3.7mm	ϕ 4.5mm	ϕ 2.8mm
Channel diameter	ϕ 1.2mm	ϕ 1.7mm	ϕ 1.2mm
Angulation (U /D)	U=70° , D=70°	U=160° , D=100°	U=180° , D=130°

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J. Conclusion

Olympus Medical Systems Corp. has performed non-clinical tests such as thermal safety, optical performance, reprocessing, mechanical durability, mechanical safety and risk analysis to confirm the safety or effectiveness of the XCHF-BP160F Choledochoscope. In addition, EMC standard and electric safety will be performed before we market it.

Furthermore, all patient contacting materials used in the device have completed biocompatibility studies with the predicate device.

When compared to the predicate devices, the XCHF-BP160F Choledochoscope does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect the safety or effectiveness. Therefore, no clinical tests have been conducted on this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2005

Ms. Laura Storms-Tyler
Executive Director
Regulatory Affairs and Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-9058

Re: K051886
Trade/Device Name: Choledochoscope, XCHF-BP160F
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBN
Dated: September 29, 2005
Received: October 4, 2005

Dear Ms. Storms-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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known) : K051886

Device Name: Choledochoscope, XCHF- BP160F

Indications for Use :

This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories (such as a biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the biliary tract and pancreatic duct in conjunction with DUODENOSCOPE with an instrument channel with a minimum diameter of ϕ 4.2mm.

Prescription Use V **AND / OR** **Over-The-Counter Use** _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051886