SEP 25 2012

510(k) SUMMARY

CHOLEDOCHO VIDEOSCOPE CHF-Y0005

1 General Information

- Applicant:

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

- Official Correspondent:

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- 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: CHF-Y0005
- Common Name: CHOLEDOCHO VIDEOSCOPE
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Choledochoscope And Accessories, Flexible Endoscope, Accessories, Narrow Band Spectrum
- Product Code: FBN, NWB

3 Predicate Device Information

Subject Device (Part of this Submission)	Predicate Device	PD's 510(k) No.
CHOLEDOCHO VIDEOSCOPE CHF-Y0005 (Hereinafter referred to as CHF-Y0005)	VIDEOSCOPE OLYMPUS XCHF TYPE T160 (XCHF-T160)	K082576
	GASTROINTESTINALVIDEOSCOPE XGIF-Q140M (XGIF-Q140M)	K032177
	CHOLEDOCHOSCOPE OLYMPUS XCHF TYPE B180Y1 (XCHF-B180Y1)	K080586
	EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE N180 (GIF-N180)	K100584

4 Device Description

The CHF-Y0005 is designed as a flexible video endoscope used for endoscopy and endoscopic surgery within the biliary tract and the duodenum.

The CHF-Y0005 is modified from the predicate XCHF TYPE T160 as it has two bending sections, a gas feeding function when connected to an Endoscopic CO_2 regulation unit, Narrow Band Imaging observation and is now compatible with specified electrosurgical units and electrosurgical accessories.

5 Indications for Use

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment. This instrument is intended to be used without a DUODENOSCOPE.

The CHOLEDOCHO VIDEOSCOPE CHF-Y0005 is indicated for endoscopy and endoscopic surgery within the biliary tract and the duodenum.

6 Comparison of Technological Characteristics

The CHF-Y0005 is basically identical to the predicate devices in intended use, and similar in specifications.

When compared to the predicate devices the subject device has the similar technological features such as the depth of field, direction of forward view and bending section angulation. The differences include two bending sections, a gas feeding function when connected to an

Endoscopic CO_2 regulation unit, Narrow Band Imaging observation and is now compatible with specified electrosurgical units and electrosurgical accessories.

7 Substantially Equivalent Discussion

The indications for use, principles of operation and fundamental technology of the CHF-Y0005 are similar to the predicate devices.

The major differences from the predicate devices are as follows:

Bending Section:
When compared with predicate XCHF-T160 device (K082576), the predicate XCHF-T160 device has one bending section with four bending directions (Up/Down/Right/Left).
The predicate device XGIF-Q140M (K032177) also has two bending sections. The first bending section has four bending directions (Up/Down/Right/Left) while the second bending section passively bends in 4 directions (Up/Down/Left/Right).
As the CHF-Y0005 has the same degree of movement as the predicate XCHF-T160.

Gas Feeding:
The gas feeding function was added to allow for insufflations with CO2 which aids in the insertion of the choleodocho scope through the GI tract.
The predicate XCHF-T160 device (K082576) does not have a gas feeding function. However, the predicate XGIF-Q140M (K032177) does have a gas feeding function.

Narrow Band Imaging:
The predicate XCHF-B180Y1 device (K080586) which has similar indications for use to the subject device, was cleared with NBI observation mode.

Compatibility with electrosurgical units:
The distal end of the subject CHF-Y0005 is equivalent to the predicate XGIF-Q140M (K032177) and therefore is compatible with the specified electrosurgical units

The above functions have been confirmed that the safety and effectiveness are equivalent as compared with the predicate devices. The CHF-Y0005 is similar or identical in the method of operation, materials and design as the predicate devices.

8 Summary of Non-Clinical Testing

The following non-clinical tests were performed.

Basic safety and performance testing was performed in accordance with IEC 60601-1, 60601-1-1, 60601-1-2, 60601-2-18. In addition, verification and comparison studies were conducted to evaluate the mechanical and functional performance.

The following standards were used during the design and validation of the subject devices.

1) IEC 60601-1: 1988, A1: 1991, A2: 1995
2) IEC 60601-1-1: 2000,
3) IEC 60601-1-2: 2001, A1: 2004
4) IEC 60601-2-18: 1996, A1: 2000
5) ISO 14971: 2007
6) ASTM E1837-96: 2007
7) ANSI/AAMI/ISO 11135-1: 2007
8) ISO 10993-7: 2008

The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of their risk analysis assessment.

9 Conclusion

When compared to the predicate device, the subject CHF-Y0005 device does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device. Therefore, the CHF-Y0005 is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Sheri Musgnung
Associate Manager, Regulatory Affairs
Olympus America Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

SEP 25 2012

Re: K113120
Trade/Device Name: CHOLEDOCHO VIDEOSCOPE CHF-Y0005
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBN, NWB
Dated: September 14, 2012
Received: September 17, 2012

Dear Ms. Musgnung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 113120

Device Name: CHOLEDOCHO VIDEOSCOPE CHF-Y0005

Indications For Use:

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The CHOLEDOCHO VIDEOSCOPE CHF-Y0005 is indicated for endoscopy and endoscopic surgery within the biliary tract and the duodenum.

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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113120