K091759

SEP 18 2009

510(k) SUMMARY

Single Use Splinting Tube
ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, ST-Y0003-H

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, M.S., 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

- Manufacturer:

  OLYMPUS MEDICAL SYSTEMS CORP. Hinode Plant
  34-3 Hirai Hinode-machi, NIshitama-gun,
  Tokyo, Japan 190-0182
  Establishment Registration No: 003637092

2 Device Identification

- Device Trade Name: SINGLE USE SPLINTING TUBE
  ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, ST-Y0003-H
- Common Name: SINGLE USE SPLINTING TUBE
- Regulation Number: 21 CFR 876.5980
- Regulation Name: Gastrointestinal tube and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology
- Product Code: KNT

3 Predicate Device Information

- Device Name: Single Use Splinting Tube ST-SB-1
- Common Name: Single Use Splinting Tube
- Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
- 510(k) No. K071254

4 Device Description

The single use splinting tube, model ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, and ST-Y0003-H used for assisting procedure of inserting a videoscope into the biliary tract , using with a VIDEOSCOPE XCHF-T160.

5 Indications for Use

This instrument has been designed to be used with a VIDEOSCOPE XCHF-T160. Use this instrument for endoscopy and endoscopic surgery within the biliary tract.

6 Comparison of Technological Characteristics

The Single Use Splinting Tube, model ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, and ST-Y0003-H are basically identical to the predicate device in intended use, and similar in specifications except for the addition of side holes. Comparison between the subject and predicate devices is shown in Table 1.

Table 1. Comparison of Specifications
Subject Device: Single Use Splinting Tube
ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, ST-Y0003-H
Predicate Device: Single Use Splinting Tube ST-SB1 (K071254)

Specifications	Subject Device ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, ST-Y0003-H	Predicate Device ST-SB1
Balloon Outer Diameter	ϕ 25 mm	ϕ 40mm
Length of Balloon	20mm	52mm
Tube Outer Diameter	ϕ 10 mm	ϕ 13.2mm
Tube Inner Diameter	ϕ 7 mm	ϕ 11mm
Total Length	1200mm	1400mm
Working Length	1120mm	1320mm
Side Holes	ST-Y0002-S, ST-Y0002-H Length: 12 x 6 mm, Shape: Oval Place: Provided on two places ST-Y0003-S, ST-Y0003-H None	None
Air flow lumen cross-section shape	Oval (1.4mm x 1.1 mm)	Rectangle (1.4 mm x 1.0 mm)
Distal tip shape	Rounded shape made of silicone rubber adhesive	Silicone rubber distal tip bonded with silicone rubber adhesive
Sterilization before shipment	Non sterile	Sterile
Balloon inflation device	Syringe	Balloon Control Unit (OBCU)

7 Conclusion

When compared to the predicate device, the Single Use Splinting Tube, model ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, and ST-Y0003-H 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 1 8 2009

OLYMPUS MEDICAL SYSTEMS CORP.
% Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs Project Manager
Olympus America, Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K091759
Trade/Device Name: Single Use Splinting Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: June 12, 2009
Received: June 22, 2009

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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091759

Device Name: SINGLE USE SPLINTING TUBE

ST-Y0002-S, ST-Y0002-H, ST-Y0003-S, ST-Y0003-H

Indications For Use:

This instrument has been designed to be used with the VIDEOSCOPE XCHF-T160 for endoscopy and endoscopic surgery within the biliary tract.

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, Abdominal,
and Radiological Devices
510(k) Number K091759