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510(k) SUMMARY

PBD-1030/1031/1032/1033 Series,
MAJ-1818/1819/1820/1821/1822 Series,
PBD-V630P/V631P/V632P Series
Single Use Biliary Drainage Stent V

February 23, 2011

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:
  Aomori Olympus Co., Ltd.
  248-1 Okkonoki 2-chome Kuroishi-shi,
  Aomori, Japan 036-0367
  Establishment Registration No.: 9614641

2 Device Identification

- Device Trade Name:
  PBD-1030/1031/1032/1033 Stent Series,
  MAJ-1818/1819/1820/1821/1822 Insertion Kit Series,
  PBD-V630P/V631P/V632P Preloaded Stent Series
  Single Use Biliary Drainage Stent V

- Common Name: Biliary catheter
- Regulation Number: 876.5010
- Regulation Name: Biliary catheter and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology/Urology
- Product Code: FGE

3 Predicate Device Information

- Device Name: PBD-3Z through 7Z
- Common Name: OLYMPUS PBD STENTS
- Manufacturer: Aomori Olympus Co., Ltd.
  248-1 Okkonoki 2-chome Kuroishi-shi,
  Aomori, Japan 036-0367
  Establishment Registration No.: 9614641
- 510(k) No. #K933200

4 Device Description

The subject Single Use Biliary Drainage Stent V PBD-1030/ 1031/ 1032/ 1033 Stent Series, MAJ-1818/ 1819/ 1820/ 1821/ 1822 Insertion Kit Series and PBD-V630P/ V631P/ V632P Preloaded Stent Series are designed to be used with Olympus endoscopes for Endoscopic Biliary Drainage(ERBD) procedure.
The subject Biliary Stent is placed into the duodenal papilla by using a Guidewire and Pusher Catheter to maintain the flow of bile by indwelling in the duodenal papilla. It is introduced to the biliary duct as follows:

1) The user pushes the distal end of the guidewire into the papilla of Vater and advance the guidewire to the target area.
2) The user inserts the guide catheter, stent and pusher catheter over the guidewire. The distal portion of the stent is inserted first.
3) The user advances the stent until the side flap at its proximal end contacts the papilla of Vater.
4) The user withdraw the guide catheter from the pusher catheter to release the stent.
5) The user withdraw the pusher catheter from the endoscope.

5 Indications for Use

This instrument has been designed to be used with Olympus Endoscopes for endoscopic retrograde biliary drainage (ERBD). The stent is not intended to be permanently implanted in the patient. The stent is intended only for short-term implantation.

6 Comparison of Technological Characteristics

The subject Single Use Biliary Drainage Stent V PBD-1030/1031/1032/1033 Stent Series, MAJ-1818/1819/1820/1821/1822 Insertion Kit Series and PBD-V630P/V631P/V632P Preloaded Stent Series are basically identical to the predicate biliary stent PBD-6Z, included in MD-274 except as
follows:

1) The stent material and a pigment have been changed.
2) The dimention and shape have been changed.
3) An accessory device, the Protection Sleeve and straightener have been added.

7 Summary of Non-Clinical Testing

The following non-clinical tests were performed:

1) Biocompatibility
   a) Cytotoxicity Test
   b) Sensitization Test
   c) Intracutaneous Reaction Test
   d) Implantation Test
   e) Subacute toxicity Test
   f) Systemic toxicity Test
   g) Chemistry special Test (60 day)
   h) Bile solution PH

2) Stability
Representative samples of devices were subjected to accelerated and real time ageing. The results of the accelerated age testing demonstrates that the device will be stable for the stated shelf-life. In addition, real time age testing will confirm the results of the accelerated age testing. The test devices were evaluated to ensure they continued to meet their specifications, including flexibility, tensile strength, tensile strength after stent placement, patency and compatibility with the endoscope.

3) Bench Testing
Bench testing was performed to compare the flexibility of the stent

4) Use of Standards
The following standards were used during the design and validation of the subject devices:

   a) ISO 14971, 2007
   b) ISO 11135-1, 2007
   c) ISO 10993-1, 2003
   d) ISO 10993-5, 1999
   e) ISO 10993-6, 1994
   f) ISO 10993-10, 2002
   g) ISO 10993-11, 2006
   h) ASTM F1980-07

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 this risk analysis assessment.

8 Conclusion

When compared to the predicate device, the PBD-1030/1031/1032/1033 Stent Series MAJ-1818/1819/1820/1821/1822 Insertion Kit Series and PBD-V630P/V631P/V632P Preloaded Stent Series 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Olympus Medical Systems Corp.
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Re: K103478
Trade/Device Name: PBD-1030/1031/1032/1033 Stent Series,
MAJ-1818/1819/1820/1821/1822 Insertion Kit Series, and
PBD-V630P/V631P/V632P Preloaded Stent Series
Single Use Biliary Drainage Stent V
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: November 23, 2010
Received: November 26, 2010

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. 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,

Herbert P. Lerner, M.D., Director (Acting)
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): K103478

Device Name:

PBD-1030/1031/1032/1033 Series, MAJ-1818/1819/1820/1821/1822 Series
PBD-V630P/V631P/V632P Series

Indications For Use:

This instrument has been designed to be used with Olympus Endoscopes for endoscopic retrograde biliary drainage (ERBD). The stent is not intended to be permanently implanted in the patient. The stent is intended only for short-term implantation.

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 K103478