October 21, 2025

Olympus Medical Systems Corporation
Eve Smith
Regulatory Affairs Specialist II
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japan

Re: K250409
Trade/Device Name: Disposable Balloon Catheter (B5-2Q); Disposable Balloon Catheter (B7-2Q); Disposable Balloon Catheter (B7-2LA)
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: September 10, 2025
Received: September 10, 2025

Dear Eve Smith:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ANTHONY LEE -S

Anthony C. Lee Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250409

Device Name

Disposable Balloon Catheter (B5-2Q);
Disposable Balloon Catheter (B7-2Q);
Disposable Balloon Catheter (B7-2LA)

Indications for Use *(Describe)*

The DISPOSABLE BALLOON CATHETER B5-2Q, B7-2Q/2LA have been designed to be used with Olympus endoscopes to inject contrast medium into the biliary or pancreatic track. They can also be used for retrieval of biliary or pancreatic stones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

For

Disposable Balloon Catheter B5-2Q, B7-2Q/2LA

General Information

Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Phone: (+81) 42-642-2111 Fax: (+81) 42-642-2307 Establishment Registration Number: 8010047
Manufacturer:	Aomori Olympus Co., Ltd. 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357, Japan
510(k) Submitter:	Olympus Corporation of the Americas 3500 Corporate Parkway Center Valley, PA 18034
Contact Person:	Eve Smith Regulatory Specialist II Mobile: (267) 373-7633 Email: eve.smith@olympus.com
Date Prepared:	October 10, 2025

Device Description

Device Name:	Disposable Balloon Catheter B5-2Q, B7-2Q/2LA
Generic/Common Name:	Stents, Drains and Dilators for the Biliary Ducts
Regulation Number:	21 CFR 876.5010
Regulatory Class:	Class II
Classification Name:	Biliary Catheter and Accessories
Product Code:	FGE
Review Panel:	Gastroenterology & Urology

Predicate Device

Device Name	510(k) Submitter	510(k) No.
Olympus B5/B7 Series Balloon Catheters	Olympus America, Inc.	K962925

Indications for Use

The DISPOSABLE BALLOON CATHETER B5-2Q, B7-2Q/2LA have been designed to be used with Olympus endoscopes to inject contrast medium into the biliary or pancreatic track. They can also be used for retrieval of biliary or pancreatic stones.

Principle of Operation

The Balloon Catheters are constructed of an inflatable balloon, tube, branch, injection port, air feeding port, and stopcock.

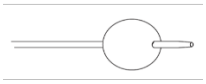
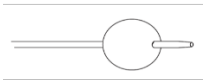
Prior to use, a sterile syringe is attached to the air feeding port and injects air into the tube to inflate the balloon to the specified volume to confirm that the balloon inflates properly. The balloon is then deflated completely, and the tube is inserted into the instrument channel of the endoscope and advanced to the target area, where the balloon is inflated to allow for biliary or pancreatic stone removal or contrast medium injection through the injection port. When the procedure is completed, the balloon is deflated and the tube is removed from the patient.

Comparison of Technological Characteristics

Table 1 compares the DISPOSABLE BALLOON CATHETER B5-2Q, B7-2Q/2LA to the predicate device with respect to intended use, and technological characteristics, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 1. Subject and Predicate Device Comparison Table

Feature / Characteristic	Subject Device (SD)	Predicate Device (PD)
	Disposable Balloon Catheter B5-2Q and B7-2Q/2LA	**Olympus B5/B7 Series Balloon Catheters (K962925)**
Indications for Use	The DISPOSABLE BALLOON CATHETER B5-2Q, B7-2Q/2LA have been designed to be used with Olympus endoscopes to inject contrast medium into the biliary or pancreatic track. They can also be used for retrieval of biliary or pancreatic stones.	The B5-2Q and B7-2Q/B7-2LA Balloon Catheters are to be used for biliary or pancreatic stone removal and dye injection associated with ERCP.
Regulation Number	876.5010	876.5010
Regulation Name	Biliary catheter and accessories.	Biliary catheter and accessories.
Regulatory Class	Class II	Class II
Product Code	FGE *Stents, drains and dilators for the biliary ducts*	FGE *Stents, drains and dilators for the biliary ducts*
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Basic principle	The Balloon Catheter is inserted into the instrument channel of the endoscope and advanced to the target	The Balloon Catheter is inserted into the instrument channel of the endoscope and advanced to the target area, where the balloon

Feature / Characteristic	Subject Device (SD) Disposable Balloon Catheter B5-2Q and B7-2Q/2LA	Predicate Device (PD) Olympus B5/B7 Series Balloon Catheters (K962925)
	area, where the balloon is inflated to allow for biliary or pancreatic stone removal or dye injection through the injection port.	is inflated to allow for biliary or pancreatic stone removal or dye injection through the injection port.
Shape of the Balloon		
Maximum Insertion Portion Diameter (mm)	B5-2Q: ø 1.95 B7-2Q: ø 2.55 B7-2LA: ø 2.55	B5-2Q: ø 1.95 B7-2Q: ø 2.55 B7-2LA: ø 2.55
Working Length (mm)	B5-2Q: 1950 B7-2Q: 1950 B7-2LA: 3500	B5-2Q: 1950 B7-2Q: 1950 B7-2LA: 3500
Diameter after inflation (mm)	B5-2Q: ø 11.0 B7-2Q: ø 13.0 B7-2LA: ø 13.0	B5-2Q: ø 11.0 B7-2Q: ø 13.0 B7-2LA: ø 13.0
Maximum Air Volume (ml [cc])	B5-2Q: 2.2 B7-2Q: 2.4 B7-2LA: 2.6	B5-2Q: 1.6 B7-2Q: 1.8 B7-2LA: 2.0
Compatible Guidewire	B5-2Q: ø 0.53mm (0.021 in) B7-2Q: ø 0.89mm (0.035 in) B7-2LA: ø 0.89mm (0.035 in)	B5-2Q: ø 0.53mm (0.021 in) B7-2Q: ø 0.89mm (0.035 in) B7-2LA: ø 0.89mm (0.035 in)
Compatible Endoscope	Working length less than 1400 mm; TJF Channel Inner Diameter ø4.2	Working length less than 1400 mm; TJF Channel Inner Diameter ø4.2
Reprocessing	Single Use	Single Use
Sterilization Method	ETO	ETO

Summary of Performance Testing

The following performance testing was conducted in support of substantial equivalence determination.

- **Reprocessing Validation Testing**

  The subject device is single use, and not reprocessed.

- **Biocompatibility Testing**

  Biocompatibility testing was conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

  - Cytotoxicity Study using the ISO Elution method
  - Intracutaneous Irritation Study
  - Guinea Pig Maximization Sensitization Test
  - Material-mediated Pyrogen Testing
  - Acute Systemic Toxicity Study in Mice

- **Electrical Safety and Electromagnetic Compatibility (EMC)**

  The Subject device does not contain any electrical parts.

- **Software and Cybersecurity**

  The subject device does not include any software.

- **Performance Testing – Bench (Non-Clinical)**

  Bench tests as listed below were conducted to ensure that the subject device performs as intended and meets design specifications.

  - Insertion of the Subject Device into the Endoscope
  - Withdrawal of the Subject Device from the Endoscope
  - Balloon Diameter after Inflation
  - Performance of Infusion
  - Strength of Junction
  - Safety Evaluation
  - Balloon Burst
  - Dimensional Analysis
  - Balloon Fatigue
  - Kink Stability
  - Radiopacity

- **Performance testing – Animal**

  No animal study was performed.

- **Performance testing – Clinical**

  No clinical study was performed.

- **Risk Management**

  Risk management was performed in accordance with ISO 14971:2019. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

Substantial Equivalence

The DISPOSABLE BALLOON CATHETER B5-2Q, B7-2Q/2LA are substantially equivalent to the legally marketed predicate device based on the claim of substantial equivalence on similarities in intended use and technological features with the predicate device:

- similar intended use
- device characteristics (design, materials, and operations) are similar or identical to the predicate device, and
- does not introduce any new or novel treatments or standard of care that differs from predicate device in commercial use.

Due to a change in the manufacturer of Natural Rubber Latex (balloon material), the subject device will hold an increased amount (volume) of air in the balloon. Although this is different between Subject Device and Predicate Device, Olympus conducted Balloon Burst, Safety Verification, and Balloon Diameter measurements/testing to confirm device safety and effectiveness.

Conclusion

In summary, the DISPOSABLE BALLOON CATHETER B5-2Q, B7-2Q/2LA is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.