



December 18, 2025

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

Re: K250993

Trade/Device Name: Single Use Cytology Brush V (BC-V600P-3010)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDX
Dated: November 3, 2025
Received: November 3, 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 Lee, Ph.D., MBA

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

Indications for Use

510(k) Number (if known)
K250993

Device Name
Single Use Cytology Brush V (BC-V600P-3010)

Indications for Use (Describe)

The Single Use Cytology Brush V BC-V600P-3010 is intended to be used to collect tissue specimens in the biliary system in combination with an endoscope.

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.

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**TRADITIONAL 510(k) NOTIFICATION
SINGLE USE CYTOLOGY BRUSH V BC-V600P-3010**

510(k) Summary

For

Single Use Cytology Brush V BC-V600P-3010

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: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507

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: March 26, 2025

Device Description

Device Name: Single Use Cytology Brush V BC-V600P-3010
Generic/Common Name: Single Use Cytology Brush
Regulation Number: 21CFR 876.1500
Regulatory Class: Class II
Classification Name: Endoscope and Accessories
Product Codes: FDX
Review Panel: Gastroenterology & Urology

Predicate Device

Device Name	510(k) Submitter	510(k) No.
Fusion Cytology Brush	Wilson-Cook Medical, Inc.	K192908



TRADITIONAL 510(K) NOTIFICATION
SINGLE USE CYTOLOGY BRUSH V BC-V600P-3010

Indications for Use

The Single Use Cytology Brush V BC-V600P-3010 is intended to be used to collect tissue specimens in the biliary system in combination with an endoscope.

Device Description

BC-V600P-3010 has been designed to collect specimens or cells endoscopically for cytologic examination in conjunction with duodenoscopes. BC-V600P-3010 is inserted into the duodenoscope through an instrument channel to reach the target area, where, by rubbing the brush on the target area, specimens or cells can be collected. BC-V600P-3010 is then withdrawn from the duodenoscope channel with the collected samples.

The handle is connected to operating wires. The grip on the handle portion controls the brush movement inside the tube. By pushing/pulling the handle, the brush at the distal end of the Subject device can be protruded from/drawn into the tube. Cells can be collected by moving over the target site with the brush.

The BC-V600P-3010 consists of:

- A. Handle
 - Grip: used to push to extend the brush from the tube. Pull to retract the brush back into the tube.
 - Operation pipe: used to connect the grip with the wires so that it can transfer the force to push/pull the brush/distal tip.
 - Locking cap: used for fixing the location of the brush by turning the locking cap clockwise.
 - Injection port: Available to attach a syringe here to inject contrast medium.
 - Hook: attached to the boot of the endoscope or ET Control Device V (sold separately).

- B. Insertion portion
 - Wires: connect operation pipe with brush and distal tip to push/pull the brush from/into the tube
 - Tube: works as the channel that the contrast media is injected through during use
 - V marking: gives the user an approximate indication of how far the instrument has been inserted into the endoscope,
 - Radiopaque marks: allow the distal end of the tube to be visualized on the X-ray monitor
 - Brush: used to brush the target area to collect samples.
 - Distal tip: When using a guidewire, the guidewire is inserted into the distal tip.

Comparison of Technological Characteristics

Table 1 provides a comparison of the intended use, device characteristics and technological features between the subject device and predicate device.

Table 1. Subject and Predicate Device Comparison Table

Feature / Characteristic	Subject Device (SD)	Predicate Device (PD)
	Single Use Cytology Brush V BC-V600P-3010	Fusion Cytology Brush (K192908)
Indications for Use	The Single Use Cytology Brush V BC-V600P-3010 is intended to be used to collect tissue specimens in the biliary system in combination with an endoscope.	This device is used for collection of cells in the biliary system.
Regulation Number	876.1500	876.1500
Regulation Name	Endoscope and Accessories	Endoscope and Accessories
Regulatory Class	Class II	Class II
Product Code	FDX (Endoscopic Cytology Brush)	FDX (Endoscopic Cytology Brush)
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Basic principle	The SD is inserted into the duodenoscope through an instrument channel to reach the target area, where, by rubbing the brush on the target area, specimens or cells can be collected. The SD is then withdrawn from the duodenoscope channel with the collected samples.	The Fusion Cytology Brush is used by passing the device through an endoscope over a prepositioned wire guide to a target location. The cytology brush is located at the distal end (patient contacting) of the device with the pin vise handle located at the proximal end (non-patient contacting). The handle is actuated by pushing the pin vise handle forward to extend the cytology brush and then pulling backward to retract the brush.
Shape of the Brush		
Minimum Accessory Channel (mm)	ø 4.2	ø 4.2
Working Length (mm)	1900	2000
Brush Diameter (mm)	ø 3	ø 3
Brush Length (mm)	10	25
Compatible guidewire (mm (inch))	ø 0.89 (0.035)	ø 0.89 (0.035)
Reprocessing	Single Use	Single Use



**TRADITIONAL 510(K) NOTIFICATION
SINGLE USE CYTOLOGY BRUSH V BC-V600P-3010**

Feature / Characteristic	Subject Device (SD)	Predicate Device (PD)
	Single Use Cytology Brush V BC-V600P-3010	Fusion Cytology Brush (K192908)
Sterilization Method	EO	EO

The Single Use Cytology Brush V BC-V600P-3010 is substantially equivalent to the legally marketed predicate device based on the claim of substantial equivalence on similarities in technological features with the predicate device:

- same 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.

The guidewire is inserted into the distal tip of the Subject Device, as opposed to the handle section of the Predicate Device. As a result, the tip shape design of the Subject Device has been changed to accommodate the insertion of the guidewire. There is no difference in the purpose and the directions for use of a guidewire, other than the method of insertion.

The brush length and number of bristles is different between the SD and the PD to meet design requirements for insertion/withdrawal forces of the SD into/from compatible endoscopes. This does not change the purpose or direction of the device.

The subject device has an added hook, locking cap and injection port that are not found on the subject device. These features were added for customer ease of use and do not change the purpose or direction of the device.

Summary of Performance Testing

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

- **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 (ISO 10993-5)
- Intracutaneous Irritation Study (ISO 10993-23)
- Guinea Pig Maximization Sensitization Test (ISO 10993-10)
- Material-mediated Pyrogen Testing (USP, <151>)
- Acute Systemic Toxicity Study in Mice (ISO 10993-11)



TRADITIONAL 510(K) NOTIFICATION
SINGLE USE CYTOLOGY BRUSH V BC-V600P-3010

- **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 and Withdrawal of the Subject Device to and from the Endoscope
- Performance after Repeated Insertion and Withdrawal
- Attachment and Detachment of Hook
- Performance after Repeated Attachment and Detachment of Hook
- Performance of Contrast Medium Infusion
- Brush Extension and Retraction from Tube
- Performance after Repeated Brush Extension and Retraction
- Locking Cap Performance
- Brush Strength
- Connection Strength

- **Animal Testing**

Olympus conducted animal testing to verify that the Subject Device's dimensions are effective to perform as a cytology brush used to collect cells in the biliary system.

In the animal test, the brush was inserted into a living pig's bile duct, scraped, and the collected samples were compared with the Predicate Device's samples to determine sufficient quantity and quality for cytology.

Conclusion

In summary, the Single Use Cytology Brush V BC-V600P-3010 is substantially equivalent to the predicate device.