June 12, 2025

Olympus Medical Systems Corporation
% Eve Smith
Regulatory Affairs Associate II
Olympus Corporation of the America
3500 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K251279
Trade/Device Name: Disposable Cytology Brush BC-202D/203D Series
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: BTG
Dated: April 24, 2025
Received: April 24, 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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | |
| Please provide the device trade name(s). | |
| DISPOSABLE CYTOLOGY BRUSH BC-202D/203D Series | |
| Please provide your Indications for Use below. | |
| The DISPOSABLE CYTOLOGY BRUSH BC-202D/203D Series is intended to be used to collect tissue specimens in the tracheobronchial tree in combination with a bronchoscope. | |
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (Part 21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |

# 510(k) Summary

## 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

Applicant Contact: Ms, Seiko Yunoki
Correspondent : Olympus Corporation of America
3500 Corporate Parkway
Center Valley, PA 18034

Date Prepared: June 10, 2025

## Device Description

| | |
|---|---|
| Device Name: | Disposable Cytology Brush BC-202D-1210/2010/3010/5010, BC-203D-2006 |
| Generic/Common Name: | Single-use Cytology Brush |
| Regulation Number: | 874.4680 |
| Regulatory Class: | Class II |
| Classification Name: | Bronchoscope (Flexible or Rigid) and accessories |
| Product Codes: | BTG |
| Review Panel: | Ear, Nose and Throat |

## Predicate Device

| Device Name | 510(k) Submitter | 510(k) No. |
|---|---|---|
| Single Use Cytology Brush BC-205D | Olympus Medical Systems Corporation | K190293 |

## Intended Use/Indications for Use

The DISPOSABLE CYTOLOGY BRUSH BC-202D/203D Series is intended to be used to collect tissue specimens in the tracheobronchial tree in combination with a bronchoscope.

## Device Description

The DISPOSABLE CYTOLOGY BRUSH BC-202D-1210/2010/3010/5010, BC-203D-2006 have been designed to collect specimens or cells endoscopically for cytologic examination in conjunction with bronchoscopes. The Subject Device (SD) is inserted into the bronchoscope through a biopsy valve to reach the target area, where, by rubbing the brush on the target area, specimens or cells can be collected. The Subject Device is then withdrawn from the bronchoscope channel with the collected samples.

The Subject Device consists of:

- Handle
- Insertion portion

The handle consists of a ring and a grip. The insertion portion consists of a plastic tube, stainless steel wire, nylon brush (length 6mm or 10mm, diameters 1.2 – 5 mm) and stainless steel distal tip. The grip is attached to the tube and the ring is attached to the wire. The user can move the brush at the tip of the wire back and forth by holding the grip and moving the ring back and forth. The distal tip is designed to prevent damage to the inside of the tube and/or bronchial wall.

**Comparison of Technological Characteristics**

**Table 1** compares the subject device to the predicate device with respect to indications for 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 Cytology Brush BC-202D-1210/2010/3010/5010, BC-203D-2006** | **Olympus Single Use Cytology Brush BC-205D K190293** |
| **Intended Use/Indications for Use** | The DISPOSABLE CYTOLOGY BRUSH BC-202D/203D Series is intended to be used to collect tissue specimens in the tracheobronchial tree in combination with a bronchoscope. | The cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with Olympus bronchoscopes with channel ϕ1.7mm or larger. |
| **Regulation Number** | 874.4680 | 874.4680 |
| **Regulation Name** | Bronchoscope (flexible or rigid) and accessories | Bronchoscope (flexible or rigid) and accessories |
| **Regulatory Class** | Class II | Class II |
| **Product Code** | BTG | BTG |
| **Classification Panel** | Ear, Nose, & Throat | Ear, Nose, & Throat |
| **Basic principle** | Pulling the ring of the operating unit will retract the brush into the tube and by pushing the ring, the brush can be extended from the tube. Cells can be collected by rubbing the target area with the brush protruding from the tube. | Pulling the ring of the operating unit will retract the brush into the tube and by pushing the ring, the brush can be extended from the tube. Cells can be collected by rubbing the target area with the brush protruding from the tube. |
| **Brush Diameter [mm]** | BC-202D-1210 = Ø1.2<br>BC-202D-2010 = Ø2.0<br>BC-202D-3010 = Ø3.0<br>BC-202D-5010 = Ø5.0<br>BC-203D-2006 = Ø2.0 | Ø2.0 |
| **Working length (mm)** | 1150 | 1150 |
| **Maximum insertion portion diameter [mm]** | BC-202D-1210, BC-202D-2010, BC-202D-3010, BC-202D-5010 = Ø1.8 | Ø1.4 |

| Feature / Characteristic | Subject Device (SD)<br>Disposable Cytology Brush BC-202D-1210/2010/3010/5010, BC-203D-2006 | Predicate Device (PD)<br>Olympus Single Use Cytology Brush BC-205D K190293 |
|---|---|---|
| | BC-203D-2006 = Ø1.1 | |
| **Brush length (mm)** | BC-202D-1210, BC-202D-2010, BC-202D-3010, BC-202D-5010 = 10<br><br>BC-203D-2006 = 6 | 10 |
| **Compatible Bronchoscope** | BC-202D-1210, BC-202D-2010, BC-202D-3010, BC-202D-5010:<br>· Length and Model: Bronchoscopes with working length of 600mm or less<br>· Bronchoscopes with Channel Inner Diameter: [mm] ø2<br><br>BC-203D-2006:<br>· Length and Model: Bronchoscopes with working length of 600mm or less;<br>· Bronchoscopes with Channel Inner Diameter: [mm] ø1.2 | · Length and Model:<br>Bronchoscopes with working length of 600mm or less<br>· Channel Inner Diameter [mm]<br>ø1.7 or more |
| **Techniques** | Transbronchial biopsy | Transbronchial biopsy |
| **Shelf-Life** | Five Years | Three Years |
| **Reprocessing** | Single Use | Single Use |
| **Sterilization Method** | EO | EO |

The DISPOSABLE CYTOLOGY BRUSH BC-202D-1210/2010/3010/5010, BC-203D-2006 are substantially equivalent to the legally marketed predicate device given the similarities in intended use/indications for use and technological features with the predicate device:

- similar intended use/indications for 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.

Dimensional changes (brush diameters, brush length) were made to the Subject Devices to maximize compatibility with the paired bronchoscopes. Although these are differences between the Subject Devices and Predicate Device, Olympus conducted Non-Clinical (Bench) Performance Testing to demonstrate substantial equivalence of the subject device to the predicate 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)

  All Biocompatibility testing passed specifications, supporting Substantial Equivalence of the Subject and Predicate devices.

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

  Bench tests as listed below were conducted to ensure that the subject device performs as intended and demonstrates substantial equivalence.

  - Expansion and Contraction of the Brush Section
  - Insertion and Withdrawal of the Subject Device from the Endoscope
  - Performance after Repeated Insertion and Withdrawal
  - Performance after Repeated Brush Strokes (quantitative force measurement)
  - Performance after Repeated Brushing (brush condition)
  - Performance after Repeated Bending
  - Brush Strength (Grip-Tube junction)
  - Brush Strength (Tip-Brush Wire junction)

  All non-clinical bench testing passed specifications, supporting Substantial Equivalence of the Subject and Predicate devices.

- **Sterilization and Shelf Life Testing**

  The Subject Device is provided sterile to the end user. The following was performed:

  • Sterilization validation per ISO 11135:2014
  • Ethylene oxide residuals per ISO 10993-7:2008

Package Integrity and Product Performance testing were conducted after simulated distribution and accelerated aging for the terminally sterilized medical device per:

• ISO 11607-1:2019, ISO 11607-2:2019 and ASTM F1980-21

The shelf life testing passed specifications, supporting Substantial Equivalence of the Subject and Predicate devices.

## Conclusion

In summary, DISPOSABLE CYTOLOGY BRUSH BC-202D-1210/2010/3010/5010, BC-203D-2006 are substantially equivalent to the predicate device.