March 4, 2025

Alton (Shanghai) Medical Instruments Co. Ltd
Wei Song
Project Engineer
No.24 Building Jinshao Rd.1688.Baoshan District
Shanghai, Shanghai 200949
China

Re: K241679
Trade/Device Name: Disposable Cytology Brush (AF series)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: BTG
Dated: January 27, 2025
Received: January 27, 2025

Dear Wei Song:

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

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)*

K241679

Device Name

Disposable Cytology Brush (AF series)

Indications for Use *(Describe)*

The cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with bronchoscopes.

Intended patient population: Adults

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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510(k) Summary

I. SUBMITTER

Name: Alton (Shanghai) Medical Instruments Co. Ltd.

Address: No.24 Building, JinShao Rd. 1688, Baoshan District, 200949 Shanghai, P. R. China

Name of contact person: Vivian Li

Position: Director of Quality Department

Tel: +86 21 56771811

Fax: +86 21 66307823

Mail: vivian@alton.com.cn

Date prepared: 2025-02-28

II. Identification of Subjective Device

Device trade name: Disposable Cytology Brush

Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories

Regulation number: 21 CFR 874.4680

Regulation class: 2

Product Code Description: brush, biopsy, bronchoscope (non-rigid)

Product code: BTG

III. Identification of Predicate device

Primary predicate device

Predicate Submission Number: K190293

Trade/Device Name: Single Use Cytology Brush BC-205D

Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories

Regulation Number: 21 CFR 874.4680

Regulatory Class: 2

Product Code Description: brush, biopsy, bronchoscope (non-rigid)

Product Code: BTG

Reference Device

Predicate Submission Number: K780872

Trade/Device Name: Cytology Brush

Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories

Regulation Number: 21 CFR 874.4680

Regulatory Class: 2

Product Code Description: brush, biopsy, bronchoscope (non-rigid)

Product Code: BTG

IV. Device description

The Disposable Cytology Brush is a sterile, single-use device as a kind of accessories for bronchial endoscopy. The Disposable Cytology Brush is intended to be used in conjunction with a bronchoscope to collect cells from the bronchi.

The Disposable Cytology Brush is designed to insert through suitable endoscope's accessory channel to collect cells from the bronchi.

The Disposable Cytology Brush mainly consists of brush head part and handle part. The brush head is composed of bullet, bristles, brush core, brush sheath, connecting tube and steel wire. The handle part is composed of hand grip and push/ pull rod.

The Disposable Cytology Brush has two different models depending on different design of the brush head. The WB series is a cytology brush with straight type of brush head and the XA series is a cytology brush with oval type of brush head. Each model has different specifications depending on different working length.

V. Indication for use

The disposable cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with bronchoscopes.

Intended patient population: Adults

VI. Comparison of technological characteristics with the predicate/reference device

Attribute	Subject device	Predicative device (K190293)	Reference device (K780872)	Discussion/Conclusion
Manufacturer	Alton (Shanghai) Medical Instruments Co. Ltd	Olympus Medical Systems Corp.	COOPERVISION, INC.	/
Trade name	Disposable Cytology Brush	Single Use Cytology Brush BC-205D	CYTOLOGY BRUSH	/
Regulation name	Bronchoscope (Flexible Or Rigid) And Accessories	Bronchoscope (Flexible Or Rigid) And Accessories	Bronchoscope (Flexible Or Rigid) And Accessories	Same
Regulatory Class	II	II	II	Same
Product code	BTG	BTG	BTG	Same
Clinical characteristics				
Indications for use	The disposable cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with bronchoscopes.	The cytology brush has been specifically designed to collect specimens or cells endoscopically for cytologic examination in conjunction with Olympus bronchoscopes with channel Φ 1.7mm or larger .	The device is intended to be used through endoscopes for the purpose of collecting sterile, non-contaminated specimens for microbiological analysis.	Same
General technological characteristics				
Device composition	The Disposable Cytology Brush mainly consists of brush head part and handle part. The brush head is	The main component of the proposed device is Brush Head, Outer Sheath and Handle.	Not publicly available	Same

Attribute	Subject device	Predicative device (K190293)	Reference device (K780872)	Discussion/Conclusion
	composed of bullet, bristles, brush core, brush sheath, connecting tube and steel wire. The handle part is composed of hand grip and push/pull rod.	The brush head is composed of bullet, bristles, brush core, brush sheath, connecting tube and steel wire. The handle part is composed of hand grip and push/pull rod.		
Principle of Operation	the subject device is inserted into bronchoscope channel to collect specimens with the brush which is equipped at the distal end of the subject device. Then users withdraw the subject device from bronchoscope channel and collect samples for cytology examination.	the subject device is inserted into bronchoscope channel to collect specimens with the brush which is equipped at the distal end of the subject device. Then users withdraw the subject device from bronchoscope channel and collect samples for cytology examination.	Same as predicate device	Same
Mechanics of action	Manual operated	Manual operated	Same as predicate device	Same
Mode of action	brush rotation	brush rotation	Same as predicate device	Same
Maximum insertion portion diameter	φ 1.8 mm	φ 1.4 mm	φ 1.8 mm	Different, see discussion 1
Working length	1000 mm, 1200 mm	1150 mm	900 mm	Different, see discussion 2
Brush diameter	AF-D1810WB/AF-D1812WB	φ 2 mm	φ 1.0 mm	AF-D1810WB/AF-D18

Attribute	Subject device	Predicative device (K190293)	Reference device (K780872)	Discussion/Conclusion
	: φ 2 mm AF-D1810XA/AF-D1812XA: φ 4 mm			12WB: same AF-D1810XA/AF-D1812XA: Different, see discussion 3
Brush length	10 mm	10mm	Not publicly disclosed	Same
Components material	Brush core: SUS304 Bristles on brush head: Nylon Sheath (tube): PTFE (Teflon) Handle: ABS	Tube: single-layer high density polymer Distal tip/Wire: stainless steel Brush: nylon Handle: not identified	Tube: two-layer Teflon catheter Plug: non-toxic water soluble wax Distal tip/Wire: not identified Brush: not identified	Different, see discussion 4
Sterilization	Method: Ethylene Oxide sterilization SAL: 10^{-6}	Method: Ethylene Oxide sterilization SAL: 10^{-6}	Same as predicate device	Same
Single use/reuse	For single use	For single use	For single use	Same
Shelf life	3 years	Not publicly disclosed	Not publicly disclosed	Different, see discussion 5

Attribute	Subject device	Predicative device (K190293)	Reference device (K780872)	Discussion/Conclusion
Mechanical performance	1) Dimension 2) Brush Bond Strength 3) Tensile Strength 4) Bronchoscope Compatibility 5) Push ability and Actuation 6) Tissue Sampling Performance	1) Brush operation with the compatible endoscope 2) Dimension of each part of the brush 3) General durability 4) Joint/tensile strength	Not publicly disclosed	Same
Biocompatibility	Cytotoxicity Skin Sensitization Skin Irritation Test Acute Systemic Toxicity Test Pyrogen Test Comply with ISO 10993 standards	Cytotoxicity Skin Sensitization Skin Irritation Test Acute Systemic Toxicity Test Pyrogen Test Comply with ISO 10993 standards	Not publicly disclosed	Same

Discussion on differences between the subject device and the predicate device

Discussion 1: there are difference on specification of maximum insertion portion diameter between both models, while considering specification of φ 1.8 mm on the subject device is same as the reference device cleared on K780872 manufactured by CooperVision, such differences will not affect clinical performance and safety of the subject device.

Discussion 2: there are two working length specification (1000 mm, 1200 mm) for the subject device, different from specification (1150 mm)for the predicate device, while considering specification of 900 mm is available on the reference device cleared on K780872 manufactured by CooperVision, specification of 1000 mm on the subject device is between the range of 1150 mm on the predicate device and 900 mm on the reference device, 1200 mm on the subject device is quite closer to 1150 mm on the predicate device. In addition, performance test comparison between the subject device and the predicate device is carried out according to specific product technical specification and the test results demonstrate substantial equivalence between subject device and predicate device. Therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 3: There are two specifications (φ2 mm and φ4 mm) related to brush diameter for the subject device. Specification for models AF-D1810WB/AF-D1812WB is φ 2 mm, same as specifications (φ2 mm) for the predicate device. while specification for models AF-D1810XA/AF-D1812XA φ 4 mm. while considering the mechanical performance tests were carried out on both the subject device and the predicate device according to specific product technical specification and the test results demonstrate substantial equivalence between subject device and predicate device. Therefore, such differences will not affect clinical performance and safety of the subject device.

Discussion 4: the tube material used in the subject device is Teflon, different from the tube material used in the predicate device (high density polymer). While considering the tube material used in the subject device is same as reference device cleared on K780872 manufactured by CooperVision, such differences will not affect clinical

performance and safety of the subject device.

Discussion 5: Although shelf life between the subject device and the predicate device is different, sterile process validation and shelf-life validation including performance test are performed on the subject device according to relevant standards, such differences will not affect the safety and effectiveness of the subject device.

VII. Summary of substantial equivalence discussion

Based on the above comparison table as well as discussion on differences, the subject device and the predicate device have similar design features and performance specifications. Although there are some differences on size specification parameters (e.g. maximum insertion portion diameter, brush diameter, working length and tube material) on the subject device and predicate device, such differences will not affect the effectiveness and safety of the subject device. In addition, a performance comparison testing between the subject device and the predicate device is implemented and all mechanical performances are verified to confirm the performance of the subject device is substantially equivalent to the predicate device. These technological differences between the subject device and the predicate device do not affect the safety and effectiveness of the subject device when used as labeled.

VIII. Summary of Non-clinical Data

Non-clinical testing for Disposable Cytology Brush was conducted to verify that the subject device met all design specifications, demonstrated safety and essential performance based on current applicable standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed.

- Biocompatibility

The biocompatibility evaluation for the Disposable Cytology Brush was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

- MTT Cytotoxicity Test: ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity

- Skin Sensitization Test: ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for irritation and sensitization
- Skin Irritation Test: ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation
- Acute Systemic Toxicity Test and Pyrogen Test: ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

➢ Sterilization Validation

The EO sterilization of the Disposable Cytology Brush has been validated according to the following applicable standards:

- ISO11135:2014+A1:2018 Sterilization of medical device- validation and routine control of ethylene oxide sterilization
- ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods-part 2: Tests of sterility performed in the validation of a sterilization process
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- USP <85> Bacterial endotoxins test

➢ Shelf Life and Sterile Barrier System

Shelf Life and Sterile Barrier System of the Disposable Cytology Brush has been validated according to the following applicable standards:

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials，sterile barrier systems and packaging systems
- ISO11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process
- ASTM F 1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D 3078-02(2013): Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

- DIN 58593-6: 2016 Sterilization – Sterile Supply – Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-16 Standard practice for performance testing of shipping containers and systems (DC-13, Level II)

➢ Performance Data – Bench

The performance tests were implemented on both the subject device (Alton Disposable Cytology Brush) and the predicate device (Olympus Single Use Cytology Brush BC-205D) to demonstrate substantial equivalence according to the specific product specification with the following test items:

- Appearance
- Size and Dimension
- Bronchoscope Compatibility
- Brush Bond Strength
- Tensile Strength
- Push ability and Actuation
- Tissue Sampling Performance

➢ Performance Data – Animal

N/A, no animal studies are available for the subject device.

IX. Summary of Clinical Data

N/A, no clinical studies are available for the subject device.

X. Conclusions

In conclusion, intended use of the subject device substantially equivalent to the predicate device quoted above. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.