March 20, 2026

Hangzhou Tappa Medical Technology Co., Ltd.
Kaixiu Peng
Regulatory Affairs
No.225, Chutian Road, Binjiang District
Hangzhou, 310000
China

Re: K251950
Trade/Device Name: Endobronchial Blocker Tube (EBT0109); Endobronchial Blocker Tube (EBT0107); Endobronchial Blocker Tube (EBT0105); Endobronchial Blocker Tube (EBT0109S); Endobronchial Blocker Tube (EBT0107S); Endobronchial Blocker Tube (EBT0105S); Endobronchial Blocker Tube (EBT0209); Endobronchial Blocker Tube (EBT0207); Endobronchial Blocker Tube (EBT0205); Endobronchial Blocker Tube (EBT0209S); Endobronchial Blocker Tube (EBT0207S); Endobronchial Blocker Tube (EBT0205S)
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: February 14, 2026
Received: February 17, 2026

Dear Kaixiu Peng:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Bradley Q. Quinn -S

Bradley Quinn
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.	K251950

Please provide the device trade name(s).

Endobronchial Blocker Tube (EBT0109);
Endobronchial Blocker Tube (EBT0107);
Endobronchial Blocker Tube (EBT0105);
Endobronchial Blocker Tube (EBT0109S);
Endobronchial Blocker Tube (EBT0107S);
Endobronchial Blocker Tube (EBT0105S);
Endobronchial Blocker Tube (EBT0209);
Endobronchial Blocker Tube (EBT0207);
Endobronchial Blocker Tube (EBT0205);
Endobronchial Blocker Tube (EBT0209S);
Endobronchial Blocker Tube (EBT0207S);
Endobronchial Blocker Tube (EBT0205S)

Please provide your Indications for Use below.

The Endobronchial Blocker Tube is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation.
The 5Fr Endobronchial Blocker Tube is indicated for pediatric populations, in children with minimum 10 Kg of weight. All other sizes are for adult use only.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

[As required by 21 CFR 807.92(c)]

1. Submission Information

510(k) Number:	K251950
Date:	March 9, 2026
Type of 510(k) Submission:	Traditional submission
Applicant:	Hangzhou Tappa Medical Technology Co., Ltd. No.225, Chutian Road, Binjiang District,Hangzhou, 310000, China
Correspondent/Consultant:	Contact: Kaixiu Peng (RA) Tel: +86 18638759164 Email: pengkx@tongpumed.com

2. Device Description

Proprietary Name:	Endobronchial Blocker Tube
Model:	EBT0109, EBT0107, EBT0105, EBT0109S, EBT0107S, EBT0105S, EBT0209, EBT0207, EBT0205, EBT0209S, EBT0207S, EBT0205S
Device Classification Name:	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)
Regulation Number:	21 CFR 868.5740
Product Code:	CBI
Device Class:	Class II
Predicate device:	K160542 & K021920 - Arndt Endobronchial Blocker Set K093888 - COOPDECH ENDOBRONCHIAL BLOCKER TUBE

3. Indications for use

The Endobronchial Blocker Tube is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 5Fr Endobronchial Blocker Tube is indicated for pediatric populations, in children with minimum 10 Kg of weight. All other sizes are for adult use only.

4. Device Description

The Endobronchial Blocker Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia. The device is composed of biologically safe materials. It is supplied sterile and intended for single use only. Widely used in combination with various endotracheal tubes, it doesn't require re-intubation at the conclusion of surgery as with a double-lumen endotracheal tube. Doctor can easily move the blocker from one side to the other and place the cuff on the target airway accurately by rotating the outside tube. The angled tip lets the blocker easily enter any bronchus and adjust position. Aspiration of secreted

material can be done via the suction port. The auto inflator can be operated with one hand to the cuff.

5. Comparison with predicate device

Comparison between proposed device and predicate device				
Comparison Items	**Subject device**	**Predicate Device 1**	**Predicate Device 2**	**Comparison**
Product name	Endobronchial Blocker Tube	5.0 Fr Arndt Endobronchial Blocker Set 9.0 Fr Arndt Endobronchial Blocker Set 7.0 Fr Endobronchial Blocker	Coopdech Endobronchial Blocker Tube	---
510(k) Number	K251950	K160542 & K021920	K093888	---
Regulation number	21 CFR 868.5740	21 CFR 868.5740	21 CFR 868.5740	Same
Product Code	CBI	CBI	CBI	Same
Classification	Class II	Class II	Class II	Same
Indication for use	The Endobronchial Blocker Tube is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 5Fr Endobronchial Blocker Tube is indicated for pediatric populations, in children with minimum 10 Kg of weight. All other sizes are for adult use only.	The Arndt Endobronchial Blocker Set is intended to differentially intubate a patient's bronchus in order to isolate the left or right lung for procedures that require one-lung ventilation. The 5.0 Fr Arndt Endobronchial Blocker is indicated for pediatric populations, in children 1 year and older. All other sizes are for adult use only.	The "COOPDECH ENDOBRONCHIAL BLOCKER TUBE" is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.	Same
Environment of Use	Hospitals OR/and ICU	Hospitals OR/and ICU	Hospitals OR/and ICU	Same
Design feature	EBT01 Series: Normal (without Auto-inflator) EBT02 Series: Auto-inflator	without Auto-inflator	Type A: without Auto-inflator Type B: with Auto-inflator	Same
Patient population	Patients requiring one lung isolation.	Patients requiring one lung isolation.	Patients requiring one lung isolation.	Same

Length (mm)	5.0 Fr: 450mm 7.0 Fr: 550mm 9.0 Fr: 550mm	5.0 Fr: 500mm, 650mm 7.0 Fr: 650mm 9.0 Fr: 650mm, 780mm	9.0 Fr: 300mm, 400mm, 500mm, 600mm, 700mm, 800mm	Similar Note 1
Outer diameter (Fr)	5.0 Fr 7.0 Fr 9.0 Fr	5.0 Fr 7.0 Fr 9.0 Fr	9.0 Fr	Same
Tip shape	Angled tip	Straight	Angled tip	Same
Catheter/Tube material	Polyamide (PA)	Polyamide (PA)	Polyamide (PA)	Same
Cuff/Balloon material	Silicone	Silicone	Silicone	Same
Cuff/Balloon shape	Cylindrical	Elliptical, Spherical	Rectangular round-shaped, Small spindle-shaped	Similar Note 2
Cuff/Balloon volume	5.0 Fr: ≤2cc 7.0 Fr: ≤3cc 9.0 Fr: ≤4.5cc Determined based on the clinical judgment of the Physician	5.0 Fr: 0.5cc ~ 2.0cc 7.0 Fr: 2.0cc ~ 6.0cc 9.0 Fr: 4.0cc ~ 8.0cc	Determined based on the clinical judgment of the Physician Rectangular round-shaped: 4.6ml Small spindle-shaped: 7.5ml Auto-inflator: Up to 8ml	Similar Note 2
Suction port material	Silicone	/	Silicone	Same
Sterilization Method	EO sterilization	EO sterilization	EO sterilization	Same
Biocompatibility	ISO 10993-1 & ISO 18562-1 Cytotoxicity Skin Irritation Sensitization Acute toxicity Pyrogen	ISO 10993-1 Cytotoxicity Skin Irritation Sensitization	ISO 10993-1	Similar Note 3
Contraindications	- Airway diameter insufficient to allow passage of the Endobronchial Blocker Tube - Bronchoscopy equipment unavailable.	- Airway diameter insufficient to allow passage of the Arndt Endobronchial Blocker - Bronchoscopy equipment unavailable	None	Same
Potential adverse event	1.Hypoxia 2.Hypoxemia 3.Tracheal injury	- Hypoxia - Tracheal and/or bronchial irritation or	1.Hypoxia 2.Hypoxemia 3.Tracheal injury	Same

	4.Endobronchial irritation or injury 5.Ventilation insufficiency including death 6.Infection (laryngitis,abscess, airway infection) 7.Traumatic injury of lip / tongue / pharyngis / trachea/glottis /carina of trachea/palate / amygdala.traumatic lesion of pharyngis	injury	4.Endobronchial irritation or injury 5.Ventilation insufficiency including death 6.Infection (laryngitis,abscess, airway infection) 7.Traumatic injury of lip / tongue / pharyngis / trachea/glottis /carina of trachea/palate / amygdala.traumatic lesion of pharyngis	

The proposed devices have the following equivalences to the predicate devices:

- Indication for use
- Environment of use
- Design feature
- Patient population
- Outer diameter
- Sterilization method
- Tip shape
- Catheter/Tube material
- Cuff/Balloon material
- Suction port material
- Contraindications
- Potential adverse event

The following technological characteristics between the predicate devices and proposed devices are not identical but are considered substantial equivalence:

- Note 1: Length

There are some differences between the length of the subject devices and the predicate devices, but its length is within Coopdech's claimed range, so this difference does not raise any safety and effectiveness issues.

- Note 2: Cuff/Balloon shape and volume

The cuff shape and inflation volume of the subject devices are slightly different from those of the predicate devices, but this will not affect its clinical use. The positioning and inflation volume of the Endobronchial Blocker Tube is usually carried out under the guidance of a fibroscope and the visual inspection of the doctor. The occlusion effect is judged in combination with the auscultation of the lungs, and the Endobronchial Blocker Tube is adjusted if necessary and then auscultated until it is correct. Therefore, this difference does not raise any safety and effectiveness issues.

- Note 3: Biocompatibility testing

The subject devices has undergone more tests to demonstrate its biosafety than the predicate devices, and this differences does not raise any safety and effectiveness issues

Therefore, the difference between the proposed devices and the predicate devices does not affect the safety or effectiveness of the device. No new risks have been identified.

6. Non-clinical Testing

All non-clinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices.

Biocompatibility test

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- USP-NF M98900_01_01 <151> Pyrogen Test (USP Rabbit Test)
- ISO 18562-1 Second Edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2 Second Edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3 Second Edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4 Second Edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

Shelf life and transportation

- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems

Packaging verification

- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM D3078-02 (Reapproved 2021)e1 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ASTM F1929-2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-2021 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 11737-2 Third edition 2019-12 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Sterilization

- ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]

Physical Performance

- ISO 5361 Fourth edition 2023-01 Anaesthetic and respiratory equipment - Tracheal tubes and connectors
- ISO 80369-20 Second edition 2024-11 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 5356-1 Third edition 2004-05-15 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
- ISO 16628 Second edition 2022-06 Anaesthetic and respiratory equipment - Tracheobronchial tubes
- ISO 18190 Second edition 2025-02 Anaesthetic and respiratory equipment - General requirements for airways and related equipment

7. Animal Testing

Substantial equivalence does not depend on animal data.

8. Clinical Testing

Substantial equivalence does not depend on clinical test data.

9. Substantial Equivalent (SE) Conclusion

The proposed device has the same intended use and the same or similar technological characteristics such as design, materials, outer diameter and sterilization method as the predicate device. Performance data demonstrates that the device functions as intended. The conclusions drawn from the nonclinical tests demonstrate that the proposed device has substantially equivalent safety and effectiveness/performance outcomes to the legally marketed predicate device.
Therefore, the proposed device is Substantial Equivalent (SE) to the predicate device.