December 14, 2023

Shenzhen Insighters Medical Technology Co., Ltd.
Kevin Huang
Official Correspondent
The 13th floor of Hengtemei Building Ganli Road No.3
Shenzhen, Guangdong 518000
China

Re: K232580
Trade/Device Name: Disposable Endobronchial Blocker Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: November 3, 2023
Received: November 6, 2023

Dear Kevin Huang:

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.

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 Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Disposable Endobronchial Blocker Tube

Indications for Use *(Describe)*
The Disposable 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 infants populations; The 7Fr Endobronchial Blocker Tube is indicated for children populations; The 9Fr Endobronchial Blocker Tube is indicated for adults use only.

Patient Population: Patients requiring one lung isolation.
Environment of Use: Hospitals-OR and ICU.

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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Section 5: 510(k) Summary

Disposable Endobronchial Blocker Tube

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date of Preparation: November 3, 2023

1. **Applicant:**

510(k) Owner's Name: Shenzhen Insighters Medical Technology Co., Ltd.
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518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
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2. **Submission Correspondent:**

Contact Person: Kevin Huang
Email: Kevin_huang1021@Sina.com
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3. **Device Information**

Device Name: Disposable Endobronchial Blocker Tube
Common Name: Endobronchial Blocker
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Classification: II
Classification Name: Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)
Product Code: CBI

4. **Predicate Device**

K093888— COOPDECH ENDOBRONCHIAL BLOCKER TUBE

5. Indications for Use

The Disposable 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 infants populations; The 7Fr Endobronchial Blocker Tube is indicated for children populations; The 9Fr Endobronchial Blocker Tube is indicated for adults use only.

Patient Population: Patients requiring one lung isolation.
Environment of Use: Hospitals-OR and ICU.

6. Device Description

The Disposable Endobronchial Blocker Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia. It is composed of blocker catheter, cuff, three-way connector, tube connector, one-way valve (with a pilot balloon) and multi-functional adaptor.

The blocker catheter has a flexible angled tip which can be easily placed into desired bronchus. It also contains a polyurethane cuff at its distal tip to create an effective seal within the inner bronchial wall and minimize potential trauma to the bronchus. The proximal end of the blocker catheter is bonded with a one-way valve and a pilot balloon assembly. This pilot balloon assembly facilitates inflation of the distal balloon and maintains inflation until it is released. The distance markings on the blocker catheter indicate how far the blocker has been advanced.

The multi-functional adaptor can be used by connecting a blocker tube to various endotracheal tubes and anesthetic circuits.

The Disposable Endobronchial Blocker Tube is available in three models: 5Fr, 7Fr and 9Fr.

The device is composed of biologically safe materials. It is supplied sterile and intended for single use only.

7. Substantial Equivalence—Comparison to Predicate Devices

A side by side comparison of the proposed device and the predicate device are provided below.

Comparison between proposed device and predicate device			
Comparison Items	Proposed Device	Predicate Device	Discussion of Differences
Devece Name	Disposable Endobronchial Blocker Tube	COOPDECH ENDOBRONCHIAL BLOCKER TUBE	Similar
510k Number	---	K093888	---
Product Code	CBI	CBI	Identical
Regulation Number	21 CFR 868.5740	21 CFR 868.5740	Identical
Regulation Name	Tracheal/Bronchial Differential Ventilation Tube	Tracheal/Bronchial Differential Ventilation Tube	Identical
Regulatory Class	Class Ⅱ	Class Ⅱ	Identical
Classification Name	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)	Identical
Indications for Use	The Disposable 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 "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.	Identical
Patient Population	Patients requiring one lung isolation	Patients requiring one lung isolation.	Identical
Environment of Use	Hospitals-OR and ICU	Hospitals-OR and ICU	Identical
Design Features	It is composed of blocker catheter, cuff, three-way connector, tube connector,	It consists of a bronchial blocker tube; advanced through an endotracheal catheter, and a joint connector,	Similar

	one-way valve (with a pilot balloon) and multi-functional adaptor.	connecting the bronchial blocker tube to the endotracheal catheter. A cuff, incorporated at the distal tip of the tube, is inflated to block the targeted bronchus.	
Lenth(mm)	600mm,695mm	300mm,400mm,500mm,600mm,700mm, 800mm	Different. The length of predicated device includes size of the proposed device. This difference does not raise any new concerns of safety and effectiveness.
Tip Shape	Angled tip	Angled tip	Identical
Used in Conjunction with Endotracheal Tube	Yes	Yes	Identical
Patient Contact Materials **Cuff**	Polyurethane	Polyurethane	Similar
Patient Contact Materials **Blocker Catheter (Tube)**	PA	Nylon	
Sterilization Method	EtO Sterilized	EtO Sterilized	Identical
Packaging	Peel pack comprises paper and film; Corrugated board outer case.	Peel pack comprises paper and film; Corrugated board outer case.	Identical
Use	Single Use, Disposable	Single Use, Disposable	Identical
Contact Duration	Less than 24h	Less than 24h	Identical
Biocompatibility	ISO 10993-1 Cytotoxicity Skin Irritation Sensitization	ISO 10993-1 Cytotoxicity Irritation Sensitization	Similar

Similarities Between Proposed and Predicate Devices

The proposed Disposable Endobronchial Blocker Tubes have the same technological characteristics as the predicate device(K093888— COOPDECH ENDOBRONCHIAL BLOCKER TUBE). The proposed and predicate device are based on the following same technological elements:

- Same intended use
- Same Indications for Use
- Same operating principals
- Same patient population
- Same Environment of Use
- Composed of biocompatible materials
- Provided sterile for single-use

• Ethylene Oxide Sterilized

The proposed Disposable Endobronchial Blocker Tube described in this 510(k) has similar technological and performance characteristics to the predicate device. The proposed device is substantially equivalent in performance, indication for use, design and materials as to predicate device. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 12 of this submission. The minor differences in the device do not introduce new issues of safety and efficacy. Changes or modifications to the device outside its intended use should not be done as this could affect the safety and effectiveness of the device.

Therefore, the proposed Disposable Endobronchial Blocker Tube are substantially equivalent to the COOPDECH ENDOBRONCHIAL BLOCKER TUBE(K093888). The proposed device has the same classification information, same indications for use and technological characteristics as compared to the predicate device.

8. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

1) Performance Testing

Performance testing was carried out to verify the safety and the effectiveness of the subject device.

Nonclinical functional performance testing was performed in accordance with:

➢ ISO 5361:2016 Anaesthetic and Respiratory Equipment-Tracheal Tubes and Connectors

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test provided in this submission include:

- Dimensions
- Cuff Resting Diameter
- Cuff herniation
- Cuff seal
- Bond strength
- Liquid leakage of one way valve
- Air leakage of one way valve
- Seal test

Testing datas and results are included in this submission, and demonstrated that the Disposable Endobronchial Blocker Tube meets all the pre-determined testing and acceptance criteria.

2) Biocompatibility

The contact duration of the proposed device Disposable Endobronchial Blocker Tube is less than 24 hours. According to ISO 10993-1:2018 Annex A Table A.1 and FDA Biocompatibility guidance, "*Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*" published on

June 16, 2016, the Disposable Endobronchial Blocker Tube is considered a Surface Device that comes in contact with the Skin for limited exposure (＜24 hours). The following tests were performed: Cytotoxicity, Intracutaneous and Sensitization.

Biocompatibility was completed on the Disposable Endobronchial Blocker Tube according to the following standards:

- ISO 10993-1:2018 - Biological Evaluation of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- ISO 10993-5:2009-Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010-Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Biocompatibility testing reports are included in this submission, and demonstrated that the device componets that are in contact with the patient are biocompatible. All evaluation acceptance criteria were met.

Conclusions Drawn from the Non-Clinical Testing

The results of these tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicate and support a determination of substantial equivalence.

9. Clinical Testing and animal testing

Clinical and animal testing were not performed for Disposable Endobronchial Blocker Tube as part of the premarket Notification requirements for this 510(k) submission and the subject of this premarket submission, Disposable Endobronchial Blocker Tube, did not require clinical and animal studies to support substantial equivalence.

10. Conclusion

The Disposable Endobronchial Blocker Tube is substantially equivalent to predicate device COOPDECH ENDOBRONCHIAL BLOCKER TUBE(K093888). Based on the indications for use, principle of operation, performance characteristics, and technological characteristics, the proposed Disposable Endobronchial Blocker Tube is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device COOPDECH ENDOBRONCHIAL BLOCKER TUBE(K093888).