May 13, 2024

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: K232529
Trade/Device Name: Disposable Double Lumen Endobronchial Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: April 10, 2024
Received: April 18, 2024

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232529

Device Name
Disposable Double Lumen Endobronchial Tube

Indications for Use *(Describe)*
The Disposable Double Lumen Endobronchial Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.
It is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.
The Disposable Double Lumen Endobronchial Tube is indicated for adults use only.

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

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

Date of Preparation: April 10, 2024

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
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3. **Device Information**

Device Name: Disposable Double Lumen Endobronchial Tube
Trade Name:
Disposable Double Lumen Endobronchial Tube (Ordinary Left Type, 28Fr, 32Fr, 35Fr, 37Fr, 39Fr, 41Fr)
Disposable Double Lumen Endobronchial Tube (Ordinary Right Type, 28Fr, 32Fr, 35Fr, 37Fr, 39Fr, 41Fr)
Disposable Double Lumen Endobronchial Tube (Visible Left Type B, 28Fr, 32Fr, 35Fr, 37Fr, 39Fr, 41Fr)
Disposable Double Lumen Endobronchial Tube (Visible Right Type B, 28Fr, 32Fr, 35Fr, 37Fr, 39Fr, 41Fr)
Disposable Double Lumen Endobronchial Tube (Visible Left Type, 28Fr, 32Fr, 35Fr, 37Fr, 39Fr, 41Fr)
Disposable Double Lumen Endobronchial Tube (Visible Right Type, 28Fr, 32Fr, 35Fr, 37Fr, 39Fr, 41Fr)
Submission Number: K232529
Submission Type: Traditional 510(k)
Common Name: Endobronchial Tube, Bronchial Tube
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/bronchial differential ventilation tube
Classification Name: Tube, Tracheal/Bronchial, Differential Ventilation (W/Wo Connector)
Device Class: II
Product Code: CBI
Review Panel: Anesthesiology

4. Predicate Device Identification

The Disposable Double Lumen Endobronchial Tube is substantially equivalent to the following predicate:

510(k) Number	Predicate Device Name	Primary Predicate
K203749	Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable	√

5. Indications for Use

The Disposable Double Lumen Endobronchial Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

It is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.

The Disposable Double Lumen Endobronchial Tube is indicated for adults use only.

6. Device Description

The Disposable Double Lumen Endobronchial Tube is a sterile, single patient use PVC Double-Lumen Endobronchial Tube (also referred to as a DLT) that is inserted into the trachea via the mouth in order to selectively ventilate one lung.

The Disposable Double Lumen Endobronchial Tube is consisted with double lumen tube with the body including 2 cuffs (Bronchial Cuff and Tracheal Cuff).

The tracheal cuff provides sealing against tracheal wall and the corresponding pilot balloon indicates state of cuff inflation/deflation. Similarly, the bronchial cuff provides sealing against bronchial wall and the corresponding pilot balloon indicates state of cuff inflation/deflation.

It is fitted with a stylet to enable shaping of the tube for navigation during intubation. When the suction is necessary, this device can be possible to be assemble with suction catheter which is 8Fr or 10Fr with PVC and this device is packaged with two suction catheters.

The Disposable Double Lumen Endobronchial Tube comes in three models, each model include two types: Ordinary Left Type, Ordinary Right Type, Visible Left Type B, Visible Right Type B, Visible Left Type, Visible Right Type. Each type will be available in six sizes: 28 Fr, 32 Fr, 35 Fr, 37 Fr, 39 Fr and 41 Fr.

The device is composed of biologically safe materials. It is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.

The Disposable Double Lumen Endobronchial Tube is indicated for adults use only.

Environments of use: Hospital-OR and ICU.

7. Substantial Equivalence—Comparison to Predicate Device

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

Table 1 – Comparison Between Proposed Disposable Double Lumen Endobronchial Tube & Predicate Ambu VivaSight 2 DLT (K203749)

Comparison between proposed device and predicate device			
Comparison Items	**Proposed Device**	**Predicate Device**	**Discussion of Differences**
Devece Name	Disposable Double Lumen Endobronchial Tube	Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable	---
510k Number	---	K203749	---
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
Device 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
Review Panel	Anesthesiology	Anesthesiology	Identical
Indications for Use	The Disposable Double Lumen Endobronchial Tube is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia. It is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery. The Disposable Double Lumen Endobronchial Tube is indicated for adults use only.	Intubation with VivaSight 2 DLT is indicated for patients with pathological lung conditions or other medical conditions that require endobronchial intubation, mechanical ventilation and isolation of one lung from the other, e.g. for thoracic surgery.	Identical. They both are designed to achieve single-lung ventilation.
Direction for Use	Prescription Use	Prescription Use	Identical
Patient Population	Patients undergoing surgical procedure requiring isolation of one lung	Patients undergoing surgical procedure requiring isolation of one lung	Identical
Environment of Use	Hospitals-OR and ICU	Hospitals-OR and ICU	Identical
Intended User	Trained Physicians	Trained Physicians	Identical
Design Features	• Double lumen shaft • Two cuffs: Bronchial Cuff and Tracheal Cuff • With visible channel, allows to insert flexible bronchoscope or laryngeal scope (O.D. less than 2.4mm) into the visible lumen for verifying tube placement and repositioning. (For Visible Type B & Visible Type) • With flushing channel, flush line with flush exits next to the visible lumen exits ensures	• Double lumen shaft • Two cuffs: Bronchial Cuff and Tracheal Cuff • With an embedded video camera and light source at the distal end of the tracheal lumen and integrated video cable with video connector. • A flush line with flush exits next to the camera lens ensures possibility for cleaning of the camera lens.	Different①

		possibility for cleaning of the camera lens. (For Visible Type) ※ The Ordinary Type does not contain visible channel and flushing channel.		
Component/ Accessory		• Endobronchial Tube • Y-connector • Suction Catheter	• Endobronchial Tube • Y-connector • Suction Catheter • Video camera and light source • Cable	
Type & Sizes (Fr; French)		**Type:** Ordinary Left Type Ordinary Right Type Visible Left Type B Visible Right Type B Visible Left Type Visible Right Type **Size:** 28 to 41 French	35 to 41 French	Different②
Cuffed		Yes	Yes	Identical
Connection to ventilation source		15mm Connector	15mm Connector	Identical
Patient Contact Materials	**Tube body**	PVC	PVC	Different③
	Tracheal tube cuff	PVC	PVC	
	Bronchial tube cuff	PVC	PVC	
	Others※	See Table 2	Unknow	
Sterilization Method		EtO Sterilized per ISO 11135	EtO Sterilized per ISO 11135	Identical
The Sterility Assurance Level		SAL 10^{-6}	SAL 10^{-6}	Identical
Packaging		Supplied individually packaged	Supplied individually packaged	Identical
Use		Single Use, Disposable	Single Use, Disposable	Identical
Biocompatibility		ISO 10993-1 Cytotoxicity Test (ISO 10993-5) Irritation Test (ISO 10993-5) Sensitization Test (ISO 10993-10)	ISO 10993-1 Cytotoxicity Test (ISO 10993-5) Irritation Test (ISO 10993-5) Sensitization Test (ISO 10993-10)	Identical

Table 2- Composition Material Informations

Type	Ordinary Left Type	Ordinary Left Type	Visible Left Type B	Visible Right Type B	Visible Left Type	Visible Right Type
No.	**Component & Meterial**	**Component & Meterial**	**Component & Meterial**	**Component & Meterial**	**Component & Meterial**	**Component & Meterial**
1	Tube body:PVC	Tube body:PVC	Tube body:PVC	Tube body:PVC	Tube body:PVC	Tube body:PVC
2	Tracheal cuff:PVC	Tracheal cuff:PVC	Tracheal cuff:PVC	Tracheal cuff:PVC	Tracheal cuff:PVC	Tracheal cuff:PVC
3	Bronchial cuff: PVC＋Color Additive: PIGMENT BLUE	Bronchial cuff: PVC＋Color Additive: PIGMENT BLUE	Bronchial cuff: PVC＋Color Additive: PIGMENT BLUE	Bronchial cuff: PVC＋Color Additive: PIGMENT BLUE	Bronchial cuff: PVC＋Color Additive: PIGMENT BLUE	Bronchial cuff: PVC＋Color Additive: PIGMENT BLUE
4	Tube body connector: PVC	Tube body connector: PVC	Tube body connector: PVC	Tube body connector: PVC	Tube body connector: PVC	Tube body connector: PVC

5	Sub tube: PVC＋Color Additive: PIGMENT BLUE	Sub tube: PVC＋Color Additive: PIGMENT BLUE	Sub tube: PVC＋Color Additive: PIGMENT BLUE	Sub tube: PVC＋Color Additive: PIGMENT BLUE	Sub tube: PVC＋Color Additive: PIGMENT BLUE	Sub tube: PVC＋Color Additive: PIGMENT BLUE
6	Sub tube connector: PP	Sub tube connector: PP	Sub tube connector: PP	Sub tube connector: PP	Sub tube connector: PP	Sub tube connector: PP
7	Sub adaptor: PP	Sub adaptor: PP	Sub adaptor: PP	Sub adaptor: PP	Sub adaptor: PP	Sub adaptor: PP
8	Endoscope adaptor: PP	Endoscope adaptor: PP	Endoscope adaptor: PP	Endoscope adaptor: PP	Endoscope adaptor: PP	Endoscope adaptor: PP
9	Cap: PVC	Cap: PVC	Cap: PVC	Cap: PVC	Cap: PVC	Cap: PVC
10	Connection tube: PVC	Connection tube: PVC	Connection tube: PVC	Connection tube: PVC	Connection tube: PVC	Connection tube: PVC
11	Three-port adaptor: PP	Three-port adaptor: PP	Three-port adaptor: PP	Three-port adaptor: PP	Three-port adaptor: PP	Three-port adaptor: PP
12	Inflating tube: PVC＋Color Additive: PIGMENT BLUE	Inflating tube: PVC＋Color Additive: PIGMENT BLUE	Inflating tube: PVC＋Color Additive: PIGMENT BLUE	Inflating tube: PVC＋Color Additive: PIGMENT BLUE	Inflating tube: PVC＋Color Additive: PIGMENT BLUE	Inflating tube: PVC＋Color Additive: PIGMENT BLUE
13	Pilot balloon: PVC＋Color Additive: PIGMENT BLUE	Pilot balloon: PVC＋Color Additive: PIGMENT BLUE	Pilot balloon: PVC＋Color Additive: PIGMENT BLUE	Pilot balloon: PVC＋Color Additive: PIGMENT BLUE	Pilot balloon: PVC＋Color Additive: PIGMENT BLUE	Pilot balloon: PVC＋Color Additive: PIGMENT BLUE
14	One-way valve: ABS + Stainless steel	One-way valve: ABS + Stainless steel	One-way valve: ABS + Stainless steel	One-way valve: ABS + Stainless steel	One-way valve: ABS + Stainless steel	One-way valve: ABS + Stainless steel
15	Adhesive: Acrylic	Adhesive: Acrylic	Adhesive: Acrylic	Adhesive: Acrylic	Adhesive: Acrylic	Adhesive: Acrylic
16	/	/	Visible channel extension tube: PVC	Visible channel extension tube: PVC	Visible channel extension tube: PVC	Visible channel extension tube: PVC
17	/	/	Airtight valve: PC	Airtight valve: PC	Airtight valve: PC	Airtight valve: PC
18	/	/	/	/	Flushing channel: PVC	Flushing channel: PVC
19	/	/	/	/	Flushing adaptor: PVC	Flushing adaptor: PVC

Similarities Between Proposed and Predicate Devices

The proposed Disposable Double Lumen Endobronchial Tube, comes in three models: Ordinary Type, Visible Type B and Visible Type, have the same technological characteristics as the predicate device (K203749—Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable). 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

Differences Between Proposed and Predicate Device

The differences between proposed and predicate device, as shown in the following:

① **Components/Accessories**

The proposed device does not include accessories such as video camera, LED light source and cable.

Although the proposed and predicate device have different accessories but the overall structure of the Endobronchial Tube is similar. Both of two Endobronchial Tube are consisted with double lumen shaft with stylet, 2 cuffs (Bronchial Cuff and Tracheal Cuff). Both of them are used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

This difference does not raise any new concerns of safety and effectiveness.

② **Model/Type/Size**

The proposed device comes in three model: Ordinary Type, Visible Type B and Visible Type while its predicate device come in one type. The three models have the same *indications for use* and principle of operation, they can be submitted in one submission. Although size of the proposed device is different with size of predicate device, the proposed device is verified by test such as appearance test, dimension test. Both of the proposed and predicate device are used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia. This difference does not raise any new concerns of safety and effectiveness.

③ **Materials**

Although the materials for patient contact components are not identical, the proposed device is verified by test such as a biocompatibility test according to ISO 10993-1, ISO 18562 and FDA Guidance ("Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process").

As a result, there are not any problems, which influence safety of the proposed device as well as influence substantial equivalence between the proposed device and predicate device. Both of them are manufactured from materials that meet all the requirements of biocompatibility.

This difference does not raise any new concerns of safety and effectiveness.

Conclusions

The proposed Disposable Double Lumen Endobronchial 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 device 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 Double Lumen Endobronchial Tube are substantially equivalent to predicate device Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable(K203749). 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 devices. 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 16628:2008 Tracheobronchial tubes - Sizing and marking
- ISO 5356-1:2004 Anesthetic and respiratory equipment – Conical connectors - Part 1: Cones and sockets
- ISO 5361:2016 Anaesthetic and Respiratory Equipment-Tracheal Tubes and Connectors
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

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

Non-Clinical Testing				
No.	Performance Test Items	Reference Standards	Acceptance Criteria	Test result
1	Dimensions	ISO 5361:2016/ ISO 16628:2008	When tested in accordance with the test method, the L1、L2、L3、OD、ID shall meet the requirements on size and tolerances.	Pass
2	Inflating tube O.D. & Angle	ISO 5361:2016	Inflating tube O.D.≤3.0mm; The angle between the inflating tube and the Endobronchial Tube at the point of separation shall not exceed 45°。	Pass
3	Cuff seal (Sealing of cuff inflating system)	/	When tested in accordance with the test method, no bubble shall be noted over the 10-s interval.	Pass
4	Cuffed tube collapse	ISO 5361:2016	When tested in accordance with the test method in ISO 5361 Annex C, the steel ball shall pass freely through the lumen of the tube.	Pass
5	Cuff herniation	ISO 5361:2016	When tested in accordance with the test method in ISO 5361 Annex D, no part of the inflated cuff shall reach beyond the nearest edge of the bevel.	Pass
6	Cuff Resting Diameter	ISO 5361:2016	When tested in accordance with the test method in ISO 5361 Annex B, at a pressure of 2 kPa, the cuff diameter shall meet the requirements on size and tolerances.	Pass
7	Air leakage of one way valve	/	When tested according to the test method, the pilot balloon should be able to naturally fill up and flat deflate.	Pass

8	Liquid leakage of one way valve	ISO 80369-7:2021	When tested in accordance with the test method, there shall be no leakage sufficient to form a falling drop of water.	Pass
9	Size of the Murphy Eye	ISO 5361:2016	The area of the Murphy eye shall be not less than 80 % of the cross-sectional area derived from the minimum inside diameter for that size tube.	Pass
10	Security of Construction of connection componants	/	When tested in accordance with the test method, the force required to detach any component permanently attached to the shaft shall be not less than that specified in standard.	Pass
11	15mm connector	ISO5356-1:2004	When tested in accordance with the test method, 15mm conical connectors shall comply with the ISO5356-1.	Pass
12	Colour Coding	ISO16628:2008	When tested in accordance with the test method, the color coding of bronchial cuff and its pilot balloon were entirely coloured blue.	Pass
13	Segment differentiation of the tracheal segment and the bronchial segments	ISO16628:2008	When tested in accordance with the test method, the segment differentiation of the tracheal segment and the bronchial segments were clearly distinguished.	Pass
14	Test for balloon diameter to inflation pressure	ISO10555-4: 2013	When tested in accordance with the test method, can reflect the relationship between balloon diameter and inflation pressure.	Pass
15	Cuff thickness	/	When tested in accordance with the test method, the cuff thickness shall meet the requirements on size and tolerances.	Pass
15	Cuff burst pressure	/	When tested in accordance with the test method, the brust pressure of the cuff shall meet the RBP 30kPa	Pass

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

2) Biocompatibility

The contact duration of the proposed device Disposable Double Lumen Endobronchial 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*", the Disposable Double Lumen Endobronchial Tube is considered a Surface Device that comes in contact with the Mucosal Membrane for limited exposure (＜24 hours).

Biological endpoints testing should be considered as following:

- Cytotoxicity

- Sensitization
- Irritation (intracutaneous reactivity)

In addition, the Disposable Double Lumen Endobronchial Tube is classified as a breathing gas-pathway device, biocompatibility evaluation of breathing gas pathways is performed in accordance with ISO 18562-1:2017 including ISO 10993-17:2002.

Based on the device categorization, the following biological effects were evaluated for the Disposable Double Lumen Endobronchial Tube.

1) General Biocompatibility (per ISO 10993-1)

No.	Test Items	Standards
1	Cytotoxicity	ISO 10993-5:2009
2	Intracutaneous test	ISO 10993-10:2010
3	Skin Sensitization	ISO 10993-10:2010

2) Biocompatibility of Breathing Gas Pathways (per ISO 18562-1)

No.	Test Items	Standards
1	Particulate Matter Emissions	ISO 18562-2:2017
2	Volatile Organic Compounds (VOCs) Emissions	ISO 18562-3:2017
3	Leachable in Condensate	ISO 18562-4:2017
4	Biological Risk Evaluation Report	ISO 18562-1:2017

Biocompatibility was completed on the Disposable Double Lumen Endobronchial 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
- ISO 10993-17:2002 - Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 18562-1:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 – Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4:2017 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

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

10. Conclusion

The Disposable Double Lumen Endobronchial Tube is substantially equivalent to predicate device Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable(K203749). Based on the indications for use, principle of operation, performance characteristics, and technological characteristics, the proposed Disposable Double Lumen Endobronchial Tube is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device Ambu VivaSight 2 DLT, Ambu VivaSight 2 Adapter Cable(K203749).