6/24/2025

Shenzhen Insighters Medical Technology Co., Ltd.
Baohong Fang
Register Manager
The 13th floor of Hengtemei Building Ganli Road No.3
518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA CHINA

Re: K242793
Trade/Device Name: Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B12A 4.6/2.0;
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B22A 5.5 /2.6;
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B26A 6.0/3.0;
Insighters™ Insight Workstation iS-PF1.
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ

Dear Baohong Fang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 5/28/2025. Specifically, FDA is updating this SE Letter to correct a typo in the device trade name and the official correspondent as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 301-796-6481, Shu-Chen.Peng@fda.hhs.gov.

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices Office of Product Evaluation and Quality Center for Devices and Radiological Health

May 28, 2025

Shenzhen Insighters Medical Technology Co., Ltd.
Baohong Fang
Register Manager
The l3th floor of Hengtemei Building, Ganli Road No. 3
Shenzhen, Guangdong 518112
China

Re: K242793
Trade/Device Name: Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B12A 4.6/2.0;
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B22A 5.5/2.6;
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B26A 6.0/3.0;
Insighters™ Insight Workstation iS-PF1
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: April 29, 2025
Received: April 30, 2025

Dear Baohong Fang:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT 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)*
K242793

Device Name
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral (iS-B12A 4.6/2.0); Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral (iS-B22A 5.5 /2.6);Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral (iS-B26A 6.0/3.0); Insighters™ Insighters Workstation (iS-PF1)

Indications for Use *(Describe)*
The Insighters™ Single-use Bronchoscope system provides images for the observation, diagnosis and treatment of trachea, bronchus and lung area.
It is indicated for diseases of the trachea and bronchi other than contraindications.
The Insighters™ Single-use Bronchoscope system is generally in-hospital use.
The Insighters™ Single-use Bronchoscope system is for use by trained clinicians/physicians 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: September 12, 2024

1. **Applicant:**

510(k) Owner's Name: Shenzhen Insighters Medical Technology Co., Ltd.
Address: The 13th floor of Hengtemei Building Ganli Road No.3
518000 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Contact Person: Bonnie Fang
Title: Regulatory Affairs
Email: fangbaohong@insighters.cn
Tel: +86 755-89313133
Fax: +86 755-84509803

2. **Submission Correspondent:**

Contact Person: Bonnie Fang
Email: fangbaohong@insighters.cn
Tel: +86 755-89313133
Fax: +86 755-84509803

3. **Device Information**

Product Name: Single-use Flexible Video Bronchoscope
Trade /Device Name:
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B12A 4.6/2.0;
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B22A 5.5 /2.6;
Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B26A 6.0/3.0;
Insighters™ Insight Workstation iS-PF1.
Common Name: Insighters™ Single-use Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Classification Name: Bronchoscope (flexible or rigid)
Review Panel: Ear Nose & Throat
Classification: Ⅱ
Product Code: EOQ

4. **Predicate Device**

K173727 — Ambu® aScope™ 4 Broncho Family

5. Indications for Use

The Insighters™ Single-use Bronchoscope System provides images for the observation, diagnosis and treatment of trachea, bronchus and lung area.
It is indicated for diseases of the trachea and bronchi other than contraindications.
The Insighters™ Single-use Bronchoscope System is generally in-hospital use.
The Insighters™ Single-use Bronchoscope System is for use by trained clinicians/physicians

only.

6. Device Description

The Single-use Flexible Video Bronchoscope (Insighters™ Single-use Bronchoscope System) consists of an Single-use Bronchoscope (iS-B12A/ iS-B22A/iS-B26A) and an Insight Workstation(iS-PF1) which is a compatible displaying unit.

The Single-use Bronchoscope consists of an insertion part (including the head end part, a bending part, and Main Hose part) and an operation part (including an electrical interface, a suction interface, a suction button, and clamp channel interface). It comes in 3 models: iS-B12A, iS-B22A, iS-B26A. The differences among the different models are only in size. This product is sterilized by ethylene oxide, single use, disposable, body orifices invasive and short-term use device.

The Insighters™ Insight Workstation (iS-PF1) consists of a display host and accessories： Power adaptor (model PH50-12)， Connection Cable. The Insight workstation supports connection with Single-use bronchoscope by Connection Cable. It can supply power and processes the images for medical electronic endoscope. It is a reusable monitor and no contact with the patient.

The Insighters™ Single-use Bronchoscope System is to provide images for the observation, diagnosis and treatment of trachea, bronchus and lung area.
This product is a portable electronic endoscope. It has the characteristics of clear image, small size, light weight, easy to carry, flexible operation, easy to learn and use, etc.
This product contains a working channel, which is convenient for use after insertion of endoscopic accessories.
The applied part of this product is the insertion part of the Single-use Bronchoscope.
Single use application of this product minimises the risk of cross-contamination of the patient.

7. Substantial Equivalence—Comparison to Predicate Devices

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

Table 1 – Comparison Between Proposed Single-use Flexible Video Bronchoscope & Predicate Ambu® aScope™ 4 Broncho Family (K173727)

Comparison between proposed device and predicate device			
Comparison Items	Proposed Device	Predicate Device	Discussion of Differences
Device Name	Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B12A 4.6/2.0; Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B22A 5.5 /2.6; Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B26A 6.0/3.0; Insighters™ Insight Workstation iS-PF1	Ambu® aScope™ 3 Slim 3.8/1.2 and Ambu® aScope™ 4 Broncho Slim 3.8/1.2; Ambu® aScope™ 3 Regular 5.0/2.2 and Ambu® aScope™ 4 Broncho Regular 5.0/2.2; Ambu® aScope™ 3 Large 5.8/2.8 and	---

		Ambu® aScope™ 4 Broncho Large 5.8/2.8; Ambu® aView Monitor	
510k Number	K242793	K173727	---
Product Code	EOQ	EOQ	Identical
Regulation Number	21 CFR 874.4680	21 CFR 874.4680	Identical
Regulation Name	Bronchoscope (Flexible Or Rigid) and accessories	Bronchoscope (Flexible Or Rigid) and accessories	Identical
Regulatory Class	Class Ⅱ	Class Ⅱ	Identical
Classification Name	Bronchoscope (flexible or rigid)	Bronchoscope (flexible or rigid)	Identical
Indications for Use	The Insighters™ Single-use Bronchoscope System provides images for the observation, diagnosis and treatment of trachea, bronchus and lung area. It is indicated for diseases of the trachea and bronchi other than contraindications. The Insighters™ Single-use Bronchoscope System is generally in-hospital use. The Insighters™ Single-use Bronchoscope System is for use by trained clinicians/physicians only.	The aScope 3 and aScope 4 Broncho endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.	Identical. They both are designed for inspection of the airways and tracheobronchial, only different expressions.
Patient Population	Adults	Adults	Identical
Environment of Use	In a hospital environment	In a hospital environment	Identical
Type of Scope	Flexible	Flexible	Identical
Bending section (°)	180↑,180↓	aScope 4: Slim-180↑,180↓ Regular-180↑,180↓ Large-180↑,160↓ aScope3: slim-130°up,130°down Regular-150°up,130°down Large-140°up, 110° down	Identical
Maximum Insertion section width Outer diameter (mm)	iS-B12A -5.0 iS-B22A -5.9 iS-B26A -6.5	aScope 4: Slim-4.3 Regular-5.5 Large-6.3 aScope3: Slim-4.3 Regular-5.5 Large-6.3	Has a similar diameter to the predicate device. The proposed device has a wider channel and a different pipe diameter ratio
Minimum instrument channel width Inner diameter (mm)	iS-B12A -2.0 iS-B22A -2.6 iS-B26A -3.0	aScope 4: Slim-1.2 Regular-2.0 Large-2.6 aScope3: Slim-1.2 Regular-2.0 Large-2.6	Identical. The proposed device has a wider channel and a different pipe diameter ratio
Working length (mm)	600	600	Identical

Field of view (°)	90°, Deviation-15%	85°	Nearly identical. The proposed device has a little bit Larger than the predicate device, for which the clinicians can see a more open view of the lesion .
Illumination method	LED	LED	Identical
Technology	When the Single-use Bronchoscope is connected with the Insight Workstation, the Insight Workstation supplies power to the Single-use Bronchoscope for data transmission. the Single-use Bronchoscope, emits light from the LED cold light source integrated into the front end of the insertion part to illuminate human tissue. The CMOS image sensor at the front end of the insertion part converts the received reflected light signal from human tissue into electrical signal data, which is transmitted to the interface of the endoscopic operation department through an internal cable. The interface is connected to the Insight Workstation through the Connection Cable provided by the Insight Workstation, and the Insight Workstation converts the received image data signal of Single-use Bronchoscope into the CMOS image signal which is presented on the screen of the Insight Workstation, and finally provides images for the observation, diagnosis and treatment of the trachea, bronchi and lung areas. The Single-use Bronchoscope system has the characteristics of clear image, small size, light weight, easy to carry, flexible operation, easy to learn and use, etc.	The flexible bronchoscope is inserted into the airways, usually through the mouth or nose. Sometimes the bronchoscope is inserted via a tracheostomy. The bronchoscopes are intended to provide images of a patient's airways and tracheobronchial tree. Images provided by the bronchoscope can be focused by adjusting the ocular on the scope's proximal housing. A video bronchoscope uses a camera located at the distal end of the scope to sense and transmit images, replacing the image guide and eyepiece. These images can then be recorded and stored on digital media.	Similar, only different expressions.
Color performance	The color performance has been tested by comparing the subject device with the predicate device.	Accurate	Identical
Image/Video capture	Yes	Yes	Identical
Single-use	Yes	Yes	Identical

Sterilization	EO sterilization, SAL $1.0x10^{-6}$	EO sterilization, SAL $1.0x10^{-6}$	Identical
Electrical Safety and Electromagnetic Compatibility	Meet the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18	Meet the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18	Identical
Biocompatibility	Meet the requirements of EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-23, EN ISO 10993-11	Meet the biological requirements	Identical
Shelf life	3 years	3 years	Identical
Package method	Paper plastic pouch (Tyvek 2FS, PET/SPE composite film)	Paper plastic pouch (Cardboard, Tyvek)	Identical
Max. resolution	1920 *1080	800 * 480	Different but safety and effectiveness are not affected
Display type	13.3 inch TFT-LCD color display	8.5” colour TFT LCD	Different but safety and effectiveness are not affected
Brightness control	Yes	Yes	Identical
Connection port	Type-C port X 4 HDMI port X 1 Headphone port X 1 Power socket X 2	USB Type A 3.5mm Jack socket (RCA adaptor cable included)	Different but safety and effectiveness are not affected

The proposed Single-use Flexible Video Bronchoscope have the same technological characteristics as the predicate devices (K173727) Ambu® aScope™ 4 Broncho Family.
The proposed and predicate devices are based on the following same technological elements:

- Same Indications for Use
- Same patient population
- Same Environment of Use
- Same Type of Scope
- Same Working length
- Same Illumination method
- Same Technology
- Same Color Performance
- A little bit different pipe diameter ratio and field of view
- Provided sterile for single-use
- Ethylene Oxide Sterilized
- They are all 3 years Shelf life
- They are all Paper plastic pouch packing

Comparison of Maximum Insertion section width Outer diameter and Minimum instrument channel width Inner diameter:

Safety Considerations:

Safety is not solely determined by the outer diameter but by the overall design and construction of the bronchoscope. Although the outer diameter of the insertion part of proposed device is slightly larger, but the channel inner diameter is wider, the overall product pipe diameter ratio is larger.

Effectiveness of Use:

The slight increase in outer diameter does not significantly affect the bronchoscope's ability to navigate through bronchial passages or to perform its intended functions. The more width inner diameter and more larger pipe diameter ratio of the proposed device, which brings good operation convenience for clinicians to change.

So this detailed explanation diameter does not compromise the product's safety or effectiveness. this diameter variation is within acceptable limits and does not adversely affect the proposed device's performance.

Comparison of Display performance

Although there are differences in the parameters of the display devices, we have conducted a comparison test of the image performance with the Predicate Device. The results showed that the images could all be displayed normally without any substantial differences, which did not affect the safety and effectiveness of the products.

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) Electrical Safety and Electromagnetic Compatibility Summary

Electrical safety and EMC testing were conducted on the proposed device. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

2) Performance Testing

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

- Optical performance testing according to ISO8600 series.
- Performance tests to document the properties of bending angle
- Aging Performance Test
- Sterile Packaging Integrity Test
- Thermal Safety Test.
- Reliability Test
- Safety testing
- Usability Test
- Chemical properties Test（RoHS/Reach）
- Photobiological Safety
- Mechanical performance Test
- Color performance test

Testing data and results are included in this submission, and demonstrated that the Single-use Flexible Video Bronchoscope meets all the pre-determined testing and acceptance criteria.

Biocompatibility Summary

Biocompatibility of the proposed device was evaluated 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" 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. The following tests were performed, as recommended:

- Cytotoxicity
- Skin Sensitization
- Intracutaneous reactivity
- Material-mediated Pyrogenicity
- Acute systemic toxicity

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

Based on the similarities of the device specifications, intended use, indications for use between the Single-use Flexible Video Bronchoscope and its predicate device, no clinical studies were needed to support this 510(k) Premarket Notification.

10. Conclusion

The non-clinical testing demonstrates that the subject device is as safe, as effective and performs as well as the predicate device. The Single-use Flexible Video Bronchoscope is substantially equivalent to the predicate device.