



May 1, 2024

Medimaging Integrated Solution, Inc. (MiiS)
Sandy Chou
Regulatory Affairs
Industry E. Rd. IV, Hsinchu Science Park,
Hsinchu, R.O.C. 3F., No.24-2
Hsinchu, 30077
Taiwan

Re: K234113

Trade/Device Name: MiiS Horus Bronchoscope; MiiS Horus Endoscope Display System -Tablet; MiiS
Horus Endoscope Display System -Video Box
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 27, 2023
Received: December 27, 2023

Dear Sandy Chou:

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,


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

Indications for Use

510(k) Number (if known)
K234113

Device Name

Bronchoscope: MiiS Horus Bronchoscope
Tablet: MiiS Horus Endoscope Display System -Tablet
Video Box: MiiS Horus Endoscope Display System -Video Box

Indications for Use (Describe)

MiiS Horus Bronchoscope:

The MiiS Horus Bronchoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system MiiS Horus Endoscope Display System -Tablet (EDS 500) or MiiS Horus Endoscope Display System -Video Box (EVS 700). The device provides endoscopic visualization of airways and tracheobronchial tree, in conjunction with displaying system to perform various endoscopic procedures.

The MiiS Horus Bronchoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.

MiiS Horus Endoscope Display System -Tablet:

The MiiS Horus Endoscope Display System -Tablet (EDS 500) is intend for use with a MiiS Horus Bronchoscope for endoscopic diagnosis treatment, and video observation.

MiiS Horus Endoscope Display System -Video Box:

The MiiS Horus Endoscope Display System -Video Box (EVS 700) is intend for use with a MiiS Horus Bronchoscope for endoscopic diagnosis treatment, and video observation.

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

Prepared: March 28, 2024

Submitter/Owner's Name/ Address Medimaging Integrated Solution Inc. (MiiS)
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Device Identification:

Trade/Device Name: Bronchoscope: MiiS Horus Bronchoscope

Tablet: MiiS Horus Endoscope Display System -Tablet

Video Box: MiiS Horus Endoscope Display System -Video Box

Common Name: Bronchoscope

Regulation Number: 21 CFR 874.4680

Regulation Name: Bronchoscope (flexible or rigid) and accessories.

Regulatory Class: Class II

Product Code: EOQ

Predicate Device:

K173727

Trade/Device Name: Ambu® aScope™ 4 Broncho

Regulation Number: 21 CFR 874.4680

Regulation Name: Bronchoscope (flexible or rigid) and accessories.

Regulatory Class: Class II

Product Code: EOQ

Description of Device:

MiiS Horus Bronchoscope (ECB 100 S/R/L) is a single-use, flexible, sterile Bronchoscope. The device provides visualization for endoscopic procedures within the airways and tracheobronchial tree.

MiiS Horus Bronchoscope (ECB 100 S/R/L) have an LED light source and a camera at the distal end of the applied part. The Bronchoscope needs to connect with its compatible display system MiiS Horus Endoscope Display System -Tablet (EDS 500) or MiiS Horus Endoscope Display System -Video Box (EVS 700) and the signal captured was then transmitted to the cable-connected display system. Both the Tablet and Video box are reusable devices.

MiiS Horus Endoscope Display System -Tablet (EDS 500) is a tablet which showing live image or snapshot from ECB 100.

MiiS Horus Endoscope Display System -Video Box (EVS 700) is a standalone imaging transfer system; it can be connected to computer to project live imaging. If needed, the pictures or videos can be storage to Tablet (EDS 500 Tablet) or computer.

There is a bending section near the region of distal end, which manipulated by the control lever on the handle part, can provide visions with more than one direction for the users.

The working channel provide access for accessories to conduct surgical procedures.

MiiS Horus Bronchoscope has been designed to be compatible with the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA).



ECB-100S (Slim): Minimum ETT inner diameter: 5.0 mm, Minimum DLT size: 35 Fr, EA minimum working channel width: up to 1.2 mm.

ECB-100R (Regular): Minimum ETT inner diameter: 6.0 mm, Minimum DLT size: 41 Fr, EA minimum working channel width: up to 2.0 mm.

ECB-100L (Large): Minimum ETT inner diameter: 7.0 mm, EA minimum working channel width: up to 2.8 mm.

Indications for Use (IFU):

MiiS Horus Bronchoscope:

The MiiS Horus Bronchoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system MiiS Horus Endoscope Display System -Tablet (EDS 500) or MiiS Horus Endoscope Display System -Video Box (EVS 700). The device provides endoscopic visualization of airways and tracheobronchial tree, in conjunction with displaying system to perform various endoscopic procedures.

The MiiS Horus Bronchoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.

MiiS Horus Endoscope Display System -Tablet:

The MiiS Horus Endoscope Display System -Tablet (EDS 500) is intend for use with a MiiS Horus Bronchoscope for endoscopic diagnosis treatment, and video observation.

MiiS Horus Endoscope Display System -Video Box:

The MiiS Horus Endoscope Display System -Video Box (EVS 700) is intend for use with a MiiS Horus Bronchoscope for endoscopic diagnosis treatment, and video observation.

Substantial Equivalence Summary

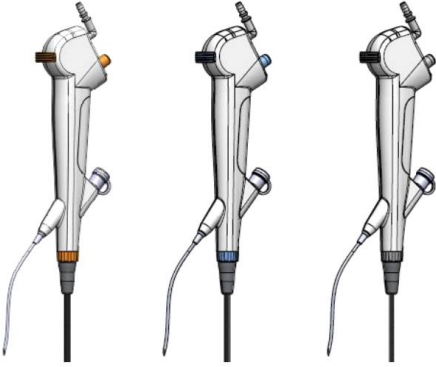

Below is a summary table comparing the IFUs and key technological characteristics between the subject and the predicate devices.

Item	Subject Device MiiS Horus Bronchoscope	Predicte Device Ambu® aScope™ 4 Broncho
Submitter	Medimaging Integrated Solution Inc.	Ambu Inc.
Model name	Bronchoscope: MiiS Horus Bronchoscope Tablet:	Ambu® aScope™ 4 Broncho



	MiiS Horus Endoscope Display System -Tablet Video Box: MiiS Horus Endoscope Display System -Video Box	
K Number	---	K173727
Product code & Classification	21 CFR 874.4680, EOQ Class II	21 CFR 874.4680, EOQ Class II
Intended use	<p>MiiS Horus Bronchoscope: The MiiS Horus Bronchoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system MiiS Horus Endoscope Display System -Tablet (EDS 500) or MiiS Horus Endoscope Display System -Video Box (EVS 700). The device provides endoscopic visualization of airways and tracheobronchial tree, in conjunction with displaying system to perform various endoscopic procedures. The MiiS Horus Bronchoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.</p> <p>MiiS Horus Endoscope Display System - Tablet: The MiiS Horus Endoscope Display System - Tablet (EDS 500) is intend for use with a MiiS Horus Bronchoscope for endoscopic diagnosis treatment, and video observation.</p> <p>MiiS Horus Endoscope Display System -Video Box: The MiiS Horus Endoscope Display System - Video Box (EVS 700) is intend for use with a MiiS Horus Bronchoscope for endoscopic diagnosis treatment, and video observation.</p>	<p>The Ambu® aScope™ 4 Broncho is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the airways and tracheobronchial tree. The endoscope is intended to provide visualization via Ambu displaying unit. The endoscope is intended for use in a hospital environment. It is designed for use in adults.</p>
Lens Specification	FOV: 120° DOV: 0° DOF: 3-50 mm	FOV: 85° DOV: 0° DOF: 6-50 mm
Mechanical Specification	<ul style="list-style-type: none"> ● Bending angle: Up: 180°/Down: 180° ● Working length: 600 mm ● Maximum Diameter of Insertion Section S: 4.2 mm R: 5.4 mm L: 6.2 mm ● Minimum Working Channel Diameter S: 1.2 mm R: 2.2 mm L: 3.0 mm ● Minimum ETT Inner Diameter Size S: 5.0 mm 	<ul style="list-style-type: none"> ● Bending angle: Up: 180°/Down: 180° ● Working length: 600 mm ● Maximum Diameter of Insertion Section S: 4.3 mm R: 5.5 mm L: 6.3 mm ● Minimum Working Channel Diameter S: 1.2 mm R: 2.0 mm L: 2.6 mm ● Minimum ETT Inner Diameter Size S: 5.0 mm



	R: 6.0 mm L: 7.0 mm ● Minimum DLT Inner Diameter Size S: 35 Fr R: 41 Fr L: N/A	R: 6.0 mm L: 7.0 mm ● Minimum DLT Inner Diameter Size S: 35 Fr R: 41 Fr L: N/A
EMC	IEC 60601-1-2	IEC 60601-1-2
Safety	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18
Bench test	ISO 8600-1 ISO 8600-3 ISO 8600-4	ISO 8600-1 ISO 8600-3 ISO 8600-4
Sterilization	EO Sterilization	EO Sterilization
LED Light source	At distal tip	At distal tip
Appearance		

Summary of the technological characteristics in comparison to the predicate devices

Similarities:

“MiiS Horus Bronchoscope” and its compatible display system (MiiS Horus Endoscope Display System Tablet (EDS 500) or MiiS Horus Endoscope Display System Video Box (EVS 700)) and the predicate device, Ambu Inc. Ambu® aScope™ 4 Broncho (K173727), have the same intended use and same mechanical specifications such as bending angle, working length, minimum endotracheal tubes (ETT) inner diameter and minimum double lumen tubes (DLT) inner diameter size.

Besides, subject Device has equivalent lens specifications such as field of view, direction of view.



Differences:

The difference lies in the mechanical specifications including diameter of insertion section and the minimum working channel diameter. The insertion section diameter is smaller 0.1 mm than predictive device. For minimum working channel diameter, the subject device is larger 0.2 ~0.4 mm, which can make the auxiliary device easier to operate. The usability proves that the difference did not raise any clinical difficulties. Thus, it is considered that there is no significance difference occurs between MiiS Horus Bronchoscope with its predicate devices.

Nonclinical Tests

The following tests have been performed in support of the substantial equivalence determination:

- Electrical safety per IEC/EN 60601-1:2005/2006+A1:2012/2013+A2:2020/2021.
- Electromagnetic Compatibility per IEC/EN 60601-1-2:2014/2015+A1:2020/2021
- Sterilization Validation per ISO 11135:2014 and ISO 11737-1:2019
- Package Integrity per ISO 11607-1:2019
- EO/ECH Residue per ISO 10993-7:2008
- Transportation test per ASTM D4169-22
- Aging test per ASTM F1980-16
- Light hazards per IEC 62471:2006
- Biocompatibility:
 - Cytotoxicity test per ISO 10993-5:2009
 - Sensitization and Irritation test per ISO 10993-10:2021
 - Material mediated pyrogenicity and systemic toxicity test per ISO 10993-11:2017
- Optical and Color performance testing

Clinical Tests

No clinical studies were performed.

Optical Radiation Safety Assessment

The MiiS Horus Bronchoscope was tested according to ISO 62471:2006 to determine acceptable light safety limits for both the illumination. The test results demonstrate the MiiS Horus Bronchoscope meets the requirements of the standard.

Conclusion

Substantial equivalence comparison and bench performance tests support the conclusion



Medimaging Integrated Solution Inc.

of substantial equivalence of MiiS Horus Bronchoscope to the predicate devices Ambu® aScope™ 4 Broncho (K173727).