September 23, 2025

Himaging Technology (Shanghai) Co., Ltd.
Shumei Xu
Registration Manager
Room 2601 and 2605 (Nominal room 2801 and 2805),
No. 418 Guiping Road, Xuhui District
Shanghai, 200233
China

Re: K251894
Trade/Device Name: Himaging Bronchscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: May 16, 2025
Received: June 20, 2025

Dear Shumei Xu:

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

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.	K251894

Please provide the device trade name(s).

Himaging Bronchscope System

Please provide your Indications for Use below.

The sterile single-use flexible video bronchoscopes are designed to be used with the Himaging endoscopic video processor, monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Himaging bronchoscope system is applicable to hospital environment or medical office environment.

The Himaging bronchoscopes are sterile single-use devices designed for use in adults.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K251894

510(k) Summary

Date of Preparation: 09/23/2025

1. Sponsor Identification

Himaging Technology (Shanghai) Co., Ltd.
Room 2601 and 2605(Nominal room 2801 and 2805), No. 418 Guiping Road, Xuhui District, 200233, Shanghai, China
Establishment Registration Number: Not assigned yet
Contact Person: Shumei Xu
Position: Registration Manager
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Email: shumei.xu@himaging.com

2. Designated Submission Correspondent

Ms. Shumei Xu (Primary Contact Person)
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Mr. Xingwang Chen (Alternative Contact Person)
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3. Identification of Subject Device

Trade Name: Himaging Bronchoscope System
Common Name: Endoscope and accessories

Regulatory Information
Classification Name: Bronchoscope (Flexible or Rigid)
Classification: II
Product Code: EOQ
Regulation Number: 21 CFR 874.4680
Review Panel: Ear Nose & Throat;

Indication for Use:
The sterile single-use flexible video bronchoscopes are designed to be used with the Himaging endoscopic video processor, monitor, endoscopic equipment and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Himaging bronchoscope system is applicable to hospital environment.

The Himaging bronchoscopes are sterile single-use devices designed for use in adults.

4. Identification of Predicate Device

K Number: K173727
Trade/Device Name: 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
Manufacturer: Ambu A/S

Indication for Use:
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.

The aScope 3 system and aScope 4 Broncho system are for use in a hospital environment.

The aScope 3 and aScope 4 Broncho are single-use devices designed for use in adults. They have been evaluated for the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA) sizes:

	Minimum ETT inner diameter	Minimum DLT size	EA minimum working channel width
aScope 3 Slim and aScope 4 Broncho Slim	5.0 mm	35 Fr	Up to 1.2 mm
aScope 3 Regular aScope 4 Broncho Regular	6.0 mm	41 Fr	Up to 2.0 mm
aScope 3 Large aScope 4 Broncho Large	7.0 mm	-	Up to 2.6 mm

Note: The predicate device has multiple models, the aScope 3 system (**aScope 3 Regular** Broncho endoscopes and Ambu ® aView Monitor) are selected to compare with the subject device.

5. Identification of Reference Device

K Number: K233671
Trade/Device Name: Ambu® aScope™ 5 Broncho 4.2/2.2, Ambu® aScope™ 5 Broncho 2.7/1.2, ,Ambu® aView™ 2 Advance

Indication for Use:
aScope™ 5 Broncho is intended for endoscopic procedures and examination within the airways and tracheobronchial tree.
aScope™ 5 Broncho is intended to provide visualization via a compatible Ambu displaying unit, and to allow passing of endotherapy instruments via its working channel.
The aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.

6. Device Description

The subject device, Himaging Bronchoscope System, is consisting of a single-use flexible video Bronchoscope and an endoscopic video processor. The subject device has been designed to be used for endoscopy within the airways and tracheobronchial tree.

7. Substantially Equivalent (SE) Comparison

Table. 1 General Comparison

ITEM	Subject Device	Predicate Device K173727	Reference Device K233671	Remark
Product Code	EOQ	EOQ	EOQ	Same
Regulation No.	874.4680	874.4680	874.4680	Same
Class	II	II	II	Same
Manufacturer	Himaging Technology (Shanghai) Co., Ltd.	Ambu A/S	Ambu A/S	Same
Product name	Himaging Bronchoscope System	aScope 3 Regular Broncho endoscopes Ambu ® aView Monitor	Ambu® aScope™ 5 Broncho 4.2/2.2 Ambu® aView™ 2 Advance	Same
Indication for Use	The sterile single-use flexible video bronchoscopes are designed to be used with the Himaging endoscopic video processor, monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Himaging bronchoscope system is applicable to hospital environment. The Himaging bronchoscopes are sterile single-use devices designed for use in adults.	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. The aScope 3 system and aScope 4 Broncho system are for use in a hospital environment. The aScope 3 and aScope 4 Broncho are single-use devices designed for use in adults.	aScope™ 5 Broncho is intended for endoscopic procedures and examination within the airways and tracheobronchial tree. aScope™ 5 Broncho is intended to provide visualization via a compatible Ambu displaying unit, and to allow passing of endotherapy instruments via its working channel. The aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.	Same
Main Configuration	Single-use flexible video bronchoscope (DBRS-100HLP)	Single-use flexible bronchoscope (Ambu® aScope™ 3	Single-use flexible bronchoscope (Ambu® aScope™ 5	Different

		Regular 5.0/2.2)	Broncho 4.2/2.2)	
	Reused Endoscopic Video Processor (HDIS-1000)	Reused Endoscopic Image Processor (Ambu® aView™ Monitor)	Reused Endoscopic Image Processor (Ambu® aView™ 2 Advance)	
Single use/ Reuse	Endoscope: Single use Image Processor: Reuse	Endoscope: Single use Image Processor: Reuse	Endoscope: Single use Image Processor: Reuse	Same
Sterile	Yes, for disposable endoscope	Yes, for disposable endoscope	Yes, for disposable endoscope	Same
Anatomical Site	Airways and tracheobronchial tree	Airways and tracheobronchial tree	Airways and tracheobronchial tree	Same
Where used	Hospitals	Hospital	Hospital	Same
Label/Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Different- Main Configuration

The endoscopic video processor of the predicate device which has an extra integrated monitor, is different from the subject device. The endoscopic video processor of the subject system is desk type, and the subject system does not include the external monitor. Based on the results of the comparing testing of image quality (color reproduction, geometric distortion, intensity uniformity, depth of field and resolution), the image quality of the subject endoscopic video processor was equivalent to that of the predicate device. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Table. 1 Specifications Comparison of Endoscopic video processor

ITEM	Endoscopic Video Processor	Endoscopic Image Processor K173727	Remark
Product name	Endoscopic Video Processor	Ambu® aView™ Monitor	
Model	HDIS-1000	aView	/
Dimension	350mm(W)×360mm (D)×92mm (H)	241mm(W)×175(H)mm×33.5(D) mm	Different
Weight	About 5Kg	1.5Kg	Different
Is there an integrated LCD display?	No	Yes	Different
Freeze	Create static picture of dynamic image	Create static picture of dynamic image	Same

Zoom	1x,2x,4x (3 levels)	The size of the live image can be changed between two sizes: 480x480 – Default setting. 560x480 – Expanded view	Different
Brightness Adjustment	Adjustment levels: 0-9	Continuous brightness adjustment	Similar
Image Saving	Able to save in internal storage or U disk (BMP or JPG format).	Able to save in internal storage or U disk.	Same
White balance	Manual	N/A	Different
Video Signal Output	DVI signal output port	JACK connector (video-out) and USB port	Different
Power Supply	It has only an external power supply, 100-240V AC, 50/60Hz, 60VA.	It has a rechargeable lithium-ion battery. It has two power supply modes, which are internal and external power supply. The external power supply is 100-240V AC, 50/60Hz, 0.6A.	Different
Communication with endoscope	Provided	Provided	Same

Different-Dimension

The dimension for the subject image processor is different form the predicate device. The dimension is just in physical specification and this difference will not raise any issues on the subject device's safety and effectiveness.

Different- Weight

The weight for the subject image processor is different form the predicate device. The weight is just in physical specification and this difference will not raise any issues on the subject device's safety and effectiveness.

Different- Is there an integrated LCD display?

The endoscopic video processor of the subject system is desk type, without an integrated LCD display. In addition, the subject system does not include the external monitor. Based on the results of the comparing testing of image quality (color reproduction, geometric distortion, intensity uniformity, depth of field and resolution), the image quality of the image processor was equivalent to that of the predicate device. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Different- Zoom

The ZOOM function of the subject image processor is different from predicate image processor. The ZOOM function is used to adjust the image size without changing the image content; this difference will not raise any issues in safety and effectiveness.

Similar- Brightness Adjustment

The brightness adjustment function of the subject image processor is different from predicate image processor. The brightness adjustment function is used to adjust the brightness without changing the image content; this difference will not raise any issues in safety and effectiveness.

Different- White balance

The subject device has the manual white balance function, is different from the predicate device which has not white balance function. The white balance function is used to generate more real color of the image without changing the image content. Based on the results of the comparing testing of image quality (color reproduction, geometric distortion, intensity uniformity, depth of field and resolution), the image quality of subject endoscopic video processor was equivalent to that of the predicate device. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Different- Video Signal Output

The types of video signal output are different between subject endoscopic video processor and predicate image processor. The subject device has DVI output port, the predicate device has JACK connector (video-out) and USB port. The image quality of the subject device and device have been tested in the quantitative image quality testing (Color Reproduction and Geometric Distortion). The test results demonstrate that the image quality of the subject endoscopic video processor was equivalent to that of the predicate device. Therefore, the difference on video signal output will not affect the safety and effectiveness of the subject device.

Different- Power Supply

The subject device is only supplied by the external power, is different from the predicate device. There are two power supplies for predicate device, which are internal and external power supply. The external power supply for subject device is same as predicate device. Therefore, the difference on power supply will not affect the safety and effectiveness of the subject device.

Table. 2 Specifications Comparison of Broncho Videoscope

ITEM	Subject Device	Predicate Device K173727	Reference Device K233671	Remark
Model	DBRS-100HLP	Ambu® aScope™ 3 Regular 5.0/2.2,	Ambu® aScope™ 5 Broncho 4.2/2.2	/

Maximum Outer Diameter of Insertion Section	5.8mm	5.5mm	/	Similar
Minimum Instrument Channel Width	2.0mm	2.0mm	/	Same
Working Channel	Φ 2.0 mm	Φ 2.0 mm	/	Same
Working Length	600mm	600mm	/	Same
Total Length	820mm	820mm	/	Same
Bending angle	Up:210°, Down:130°	Up:150°, Down:130°	/	Similar
Rotary function	120°	N/A	120°	Same
Field of View	100°	85°	/	Similar
Depth of Field	2～100mm	8～19mm	/	Different
Endoscope Illumination	LED light is placed at the distal end of the endoscope	LED light is placed at the distal end of the endoscope	/	Same
Method of Sterilization	EO	EO	/	Same

Similar- Maximum Outer Diameter of Insertion Section

The maximum outer diameter of insertion part of subject device is similar as the predicate device. Meanwhile, based on ISO 8600 Testing, the test results of maximum insertion portion width demonstrate the subject device meets the product design requirements. Therefore, this item will not affect the safety and effectiveness of the subject device.

Different- Bending angle

The bending angle of subject device is similar as the predicate device. Meanwhile, based on Function Testing of Single-use Flexible Video Bronchoscope, the test results of bending angle demonstrate the subject device meets the product design requirements. Therefore, this item will not affect the safety and effectiveness of the subject device.

Same- Rotary function

The subject device has an extra rotary function than the predicate device aScope 3, but the rotary function of subject device is same as the aScope 5 of Reference Device K233671. Therefore, the difference will not affect the safety and effectiveness of the subject device.

Similar- Field of View

The field of view of subject device is similar as the predicate device. Meanwhile, based on ISO 8600 Testing, the test results of field of view demonstrate the subject device meets the product design requirements. Therefore, this item will not affect the safety and effectiveness of the subject device.

Different- Depth of Field

The depth of field of subject device is different from the predicate device. Meanwhile, based on Resolution and Depth of Field Testing, the subject device has good resolution in the intended depth of field. Therefore, this item will not affect the safety and effectiveness of the subject device.

Table. 3 Safety Comparison

ITEM	Subject Device	Predicate Device K173727	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Particular requirements	Comply with IEC 60601-2-18	Comply with IEC 60601-2-18	Same
Patient Contact Material			
Working channel port	PP	Unknown	Different
Suction connector	PP		
Insertion cord (main hose)	Pebax		
Bending section	Silicone rubber Gray color masterbatch		
Working channel exit	TPU		
Camera Lens	Glass		
Transparent cover	PC		
Camera seat	PC with 1% Black color masterbatch		
Two-way stopcock	PC		
Luer taper	PP		
Biopsy cap	Silicone rubber		
Snake bone rubber	Silicone rubber Gray color masterbatch		
Blocking clamp tube	TPU		
Water gas 3-way tube	PP		
Water gas extension tube	TPU		
Device extension tube	Pebax		
Device 3-way	PP		
Multi-lumen tube	Pebax		

Steel ring	SUS 304		
Working channel tube	TPU		
Biocompatibility	No Cytotoxicity	No Cytotoxicity	Same
	No Sensitization	No Sensitization	
	No Irritation	No Irritation	
Sterilization (Single-use Broncho Videoscope)			
Method	EO sterilization	EO sterilization	Same
SAL	10^{-6}	10^{-6}	Same

Different - Patient-contact material

The patient-contact material of the predicate device is unknown. However, the biocompatibility tests were conducted on the subject device and the test results show that the patient-contact materials of the subject device do not raise the adverse effect on the patient. The subject device is biocompatible and conforms to ISO 10993 series standards. Therefore, the difference on the patient-contact material will not affect the safety and effectiveness of the subject device.

8. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the subject device met all design specifications and was Substantially Equivalent (SE) to the predicate device.

Performance testing:

The optical performance comparison test was conducted on the aged and un-aged Single-use Flexible Video Bronchoscope and un-aged predicate device. The test results demonstrate that the optical performance of the un-aged endoscope is similar to those of the predicate device, and those of aged endoscope is similar as those of the un-aged endoscope and the optical performance of subject device complies with the product design requirements.

The subject device was tested per the following standard, to evaluate Surface and edges, Maximum insertion portion width, Minimum instrument channel width and FOV.

- ISO 8600-1:2015 Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements
- ISO 8600-3: 2019 Endoscopes - Medical endoscopes and endotherapy devices - Part 3: Determination of field of view and dire
- ISO 8600-4:2014 Endoscopes - Medical endoscopes and endotherapy devices - Part 4: Determination of maximum width of insertion portion
- CIE ISO 11664-2:2022 Colorimetry - Part 2: CIE standard illuminants
- CIE ISO 11664-6:2022 Colorimetry - Part 6: CIEDE2000 colour-difference formula

The test results demonstrate that the subject device complies with the product design requirements.

The air/water supply test has been conducted on the subject device and predicate device. The test results demonstrate that air/water supply performance of the subject device is similar to those of the predicate device and the air/water supply performance of subject device complies with the product design requirements.

The leakage test of the air/water connector has been conducted on the subject device. The test results demonstrate that the subject device complies with the product design requirements.

The subject device is tested per IEC 62471:2006 Photobiological safety of lamps and lamp systems standard, to evaluate photobiological safety. The test result demonstrated that the subject system complies with the standard requirements.

Sterilization:
EO/ECH residual testing was conducted on the subject device per ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.

Shelf life:
A maximum shelf life of 2 years has been assigned to the subject endoscope. In order to demonstrate substantial equivalence between the subject and predicate device, the sponsor conducted accelerated aging on the subject device and performed the following tests on the accelerated aged device to provide data for the device shelf life:

- ASTM F1980-2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
  - Package integrity of aged device;
  - Product performance testing

Packaging integrity:
The package integrity performances of the subject sterility maintenance package include visual inspection, seal strength and dye penetration resistance. The test results demonstrated that the subject device complies with the following standards:

- ASTM F88/F88M-21, Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration.
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Shipping:
A simulated transportation test was conducted on the subject device. The test results demonstrated that the subject device complies with the following standards:

- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Biocompatibility

Biocompatibility of the subject Himaging Video Bronchoscope System 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 test results demonstrated that the subject device complies with the following standards:

- 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 10993-10:2021 Biological evaluation of medical devices-Part 10: Tests for skin sensitization

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device Himaging Video Bronchoscope System. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-2-18 :2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2 :2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Software Verification and Validation Testing

Software verification and validation testing were conducted on the subject device. The test results demonstrated that the subject device complies with the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Cybersecurity testing

Cybersecurity testing was conducted on the subject device. The test results demonstrated that the subject device complies with the FDA's Guidance entitled "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" Document issued on June 27, 2025.

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.