March 25, 2026

Zhuhai Wesee Meditech Co., Ltd.
Ruiliang Xie
Management Representative
3-301, 178 Dingxing Road, Tangjiawan Town, Hitech Zone
Zhuahai, Guangdong 519085
China

Re: K253184
Trade/Device Name: Video Rhinolaryngoscope System (Disposable Video Rhinolaryngoscope SP11A Endoscopic Video Processor M110B)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: September 26, 2025
Received: September 26, 2025

Dear Ruiliang Xie:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.	K253184

Please provide the device trade name(s).

Video Rhinolaryngoscope System (Disposable Video Rhinolaryngoscope SP11A
Endoscopic Video Processor M110B)

Please provide your Indications for Use below.

The Disposable Video Rhinolaryngoscope SP11A is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is used in conjunction with the Endoscopic Video Processor (Models M110B) to provide the images. The endoscope is intended for use in a hospital environment. It is designed for use in adults.

The Endoscopic Video Processor M110B is used in conjunction with corresponding Wesee endoscopes to process and display images for endoscopic procedure.

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)

510(k) Summary

510(k) Number: K253184
Date of Preparation: 03/25/2026

1. Sponsor Identification

Zhuhai Wesee Meditech Co., Ltd.
3-301, 178 Dingxing Road, Tangjiawan Town, Hitech Zone, Zhuhai, Guangdong. China
Establishment Registration Number: Not assigned yet
Contact Person: Ruiliang Xie
Position: Management Representative
Tel: +86- 07566286262
Email: xie_rl@weseemed.com

2. Designated Submission Correspondent

Mr. Ruiliang Xie
Zhuhai Wesee Meditech Co., Ltd.
P.O. Box 3-301, Zhuhai, 519085, China
Tel: +86- 07566286262
Email: xie_rl@weseemed.com

3. Identification of Subject Device

Trade Name: Video Rhinolaryngoscope System (Disposable Video Rhinolaryngoscope SP11A Endoscopic Video Processor M110B)
Common Name: Video Rhinolaryngoscope System

Regulatory Information
Classification Name: Nasopharyngoscope (flexible or rigid) and accessories
Classification: II
Product Code: EOB
Regulation Number: 21 CFR 874.4760
Review Panel: Ear Nose & Throat;

Indication for Use:
The Disposable Video Rhinolaryngoscope SP11A is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is used in conjunction with the Endoscopic Video Processor (Models M110B) to provide the

images. The endoscope is intended for use in a hospital environment. It is designed for use in adults.

The Endoscopic Video Processor M110B is used in conjunction with corresponding Wesee endoscopes to process and display images for endoscopic procedure.

4. Identification of Predicate Device

Predicate Device 1:
K Number: K191080
Trade/Device Name: Ambu® aScope TM 4 RhinoLaryngo Slim

Indication for Use:
The endoscope is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via a monitor.
The endoscope is intended for use in a hospital environment. It is designed for use in adults.

Predicate Device 2:
K Number: K223299
Trade/Device Name: Ambu® aView™ 2 Advance
Indication for Use:
The Ambu® aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.

5. Device Description

The Video Rhinolaryngoscope System consists of the Disposable Video Rhinolaryngoscope SP11A, Video Cable, Endoscopic Video Processor M110B and Accessories. To avoid risk of cross-contamination, the insertion part of the Disposable Video Rhinolaryngoscope SP11A is designed as a sterile, single use device. And other parts of the subject system are reusable device.

The endoscope has a long, thin, flexible tube to enter the patient's body, and the CMOS sensor embedded in the distal end of the endoscope is used to capture video signals of body cavity and real-time transfer the video signals to the endoscopic video processor through the video cable. The endoscopic video processor receives and processes the video signals according to the surgeon's operation on the control panel of the video image processor. Meanwhile, the light emitting diode (LED) lamp of the endoscope provides an illumination for the body cavity and the clear video is displayed on the monitor.

6. Substantially Equivalent (SE) Comparison

Table 1. General Comparison

ITEM	Subject Device	Predicate Device 1 K191080	Predicate Device 2 K223299	Remark
Product Code	EOB	EOB	EOQ	Similar
Regulation Number	21 CFR 874.4760	21 CFR 874.4760	21 CFR 874.4680	Similar
Class	II	II	II	Same
Manufacturer	Zhuhai Wesee Meditech Co., Ltd.	Ambu A/S	Ambu A/S	/
Product name	Video Rhinolaryngoscope System	Ambu® aScope™ 4 RhinoLaryngo Slim	Ambu® aView™ 2 Advance	/
Indication for Use	The Disposable Video Rhinolaryngoscope SP11A is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is used in conjunction with the Endoscopic Video Processor (Models M110B) to provide the images. The endoscope is intended for use in a hospital environment. It is designed for use in adults.	The endoscope is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via a monitor. The endoscope is intended for use in a hospital environment. It is designed for use in adults.	/	Same
	The Endoscopic Video Processor M110B is used in conjunction with corresponding Wesee endoscopes to process and display images for endoscopic procedure.	/	The Ambu® aView™ 2 Advance is intended to display live imaging data from compatible Ambu visualization devices.	

Single use/ Reuse	Endoscope: Single use Image Processor: Reuse	Endoscope: Single use	Image Processor: Reuse	Same
Sterile	The endoscope is sterile. The image processor is non- sterile	The endoscope is sterile.	The image processor is non-sterile	Same
Anatomical Site	Nasal lumens and upper airway	Nasal lumens and upper airway	/	Same
Where used	Hospitals	Hospitals	Hospitals	Same
Label/Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Similar-Product Code and Regulation Number

The predicate device 2's Product Code and Regulation Number refer to the bronchoscope and accessories. However, the Ambu® aView™ 2 Advance was also cleared for use with other compatible Ambu devices including the previously-cleared Ambu® aScope™ 4 RhinoLaryngo Slim. Therefore, the Ambu® aView™ 2 Advance can be used as the predicate device for the subject Endoscopic Video Processor (Models M110B).

Table 2. Specifications Comparison of Disposable Video Rhinolaryngoscope

ITEM	Subject Device	Predicate Device 1 K191080	Remark
Product name	Disposable Video Rhinolaryngoscope	Ambu® aScope™ 4 RhinoLaryngo Slim	/
Model	SP11A	Ambu® aScope™ 4 RhinoLaryngo Slim	/
Illumination method	LED on the distal end	LED on the distal end	Same
Distal end diameter	3.2mm	3.5mm	Similar
Maximum diameter of insertion portion	3.6mm	3.5mm	Similar
Working length	300mm	300mm	Same
Working channel	No working channel	No working channel	Same
Field of View	110°	85°	Different
Depth of Field	3mm～50mm	6mm～50mm	Similar
Bending of insertion portion	130° up, 130° down	130° up, 130° down	Same
Method of	EO	EO	Same

Sterilization			
SAL	10^{-6}	10^{-6}	Same

Similar-Distal end diameter

The distal end diameter of subject endoscope is similar as that of the predicate endoscope. The slight difference on distal end diameter will not affect the safety and effectiveness of the subject device.

Similar-Maximum diameter of insertion portion

The maximum outer diameter of insertion part of subject endoscope is similar as the predicate endoscope. Meanwhile, based on ***ISO 8600 Testing***, the test results of distal end diameter 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-Field of View

The field of view of subject endoscope is larger than that of the predicate endoscope. 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.

Similar-Depth of Field

The depth of field of subject endoscope is similar as that of the predicate endoscope. Meanwhile, based on ***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. Specifications Comparison of Endoscopic Video Processor

ITEM	Subject Device Endoscopic Video Processor	Predicate Device 2 Endoscopic Image Processor K223299	Remark
Product name	Endoscopic Video Processor	Ambu® aView™ 2 Advance	/
Model	M110B	Ambu® aView™ 2 Advance	/
Dimension	267mm (W) × 47mm (D) × 200mm (H)	331mm (W) × 52mm (D) × 215mm (H)	Similar
Display screen	10.1”	12.8”	Different
Orientation	Landscape	Landscape	Same
Storage medium	SD card	USB drive	Different
Video output port	HDMI	HDMI 3G-SDI	Similar
Power supply	built-in lithium battery or power grid via the power adaptor.	built-in lithium battery or power grid via the power adaptor.	Same

Similar- Dimension

The dimension of subject endoscopic video processor is slightly smaller than that of the predicate device. The differences on dimension will not affect the safety and effectiveness of the subject device.

Different-Display screen

The display screen of the subject device is different from that of the predicate device. Based on the ***optical performance testing*** (resolution, depth of field, noise and dynamic range, color reproduction, intensity uniformity, image frame frequency and system delay, geometric distortion), the optical performances of the subject system were similar to those of the predicate system. Therefore, the difference on display screen size will not affect the safety and effectiveness of the subject device.

Different-Storage medium

The subject device and predicate device have different storage medium. Considering both SD card and USB drive are common storage mediums, this difference on storage medium will not affect the safety and effectiveness of the subject device.

Similar-Video output

The subject device has HDMI video output port, while the predicate device has HDMI and 3G-SDI video output ports. The optical performance was conducted by using the HDMI video output port, based on the ***optical performance testing*** (resolution, depth of field, noise and dynamic range, color reproduction, intensity uniformity, image frame frequency and system delay, geometric distortion), the optical performances of the subject system were similar to those of the predicate device by using the HDMI video output port. Therefore, the difference on video output port will not affect the safety and effectiveness of the subject device.

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7. 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 devices.

<u>Electrical Safety</u>

Comply with IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

<u>EMC</u>

Comply with 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

<u>Endoscope requirements</u>

Comply with IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements

for the basic safety and essential performance of endoscopic equipment

Shelf life of endoscope

In order to ensure the safety and effectiveness of subject endoscope in the shelf life, the sponsor conducted accelerated aging on the subject endoscope and performed the testing in term of package integrity before aging and after simulated distribution, package integrity after accelerated aging, optical performance testing before aging and after accelerated aging to provide valid data for the endoscope's shelf life per the following standard.

ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM F88/F88M-23, Standard Test Method for Seal Strength of Flexible Barrier Materials.

ASTM F1929-23 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

Service life of Endoscopic Video Processor

In order to ensure the safety and effectiveness of Endoscopic Video Processor in the service life, the sponsor conducted accelerated aging on the subject Endoscopic Video Processor and performed the function and performance testing to provide valid data for the Endoscopic Video Processor's service life.

Endoscope Performance Testing

The subject device was tested per the following standard, to evaluate Surface and Edges, Maximum insertion portion width, Field of View and Direction of View, Bending Angle. The test results demonstrate that the subject device complies with the product design requirements.

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 8600-4:2023 Endoscopes - Medical endoscopes and endotherapy devices -Part 4: Determination of maximum width of insertion portion

Photobiological Safety Testing

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.

Biocompatibility

Comply with 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 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the subject device is substantially equivalent compared to the legally marketed predicate devices.