February 15, 2024

Hunan Endoso Life Technology Co., Ltd.
℅ Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza
555 West Guangzhong Road
Shanghai, 200072
China

Re: K231107
Trade/Device Name: Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 16, 2024
Received: January 17, 2024

Dear Kyra Kang:

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,

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

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)*
K231107

Device Name
Bronchoscope System

Indications for Use *(Describe)*
The Single-use Bronchoscopes have been designed to be used with the Monitor for Single-Use Endoscopy, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Bronchoscope System is for use in a hospital environment.
The Single-use Bronchoscope is a disposable device designed for use in adults.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:	February 13, 2024
Manufacturer:	Hunan Endoso Life Technology Co., Ltd. The 4th floor, Building 10, Innovation and Entrepreneurship Center, No. 31, Dongfeng Road, Economic and Technological Development Zone, Xiangtan, Hunan Province 411200, P. R. China
Contact Person:	Wang Fu RA Manager Hunan Endoso Life Technology Co., Ltd. Tel: （86）0731-52331999 Email: services@endoso.com.cn Or wangfu@endoso.com.cn
Submission Correspondent:	Ms.Kyra Kang Landlink Healthcare Technology (Shanghai) Co., Ltd. Email: kyra.kang@landlink-health.com

Identification of the Device:

Proprietary/Trade Name:	Single-use Bronchoscope, Monitor for Single-Use Endoscopy, Bronchoscope System
Model:	Single-use bronchoscope: BC12-1, BC12-2, BC20-1, BC20-2, BC22-1, BC22-2, BC22-3, BC28-1, BC28-2, BC28-3 Monitor for Single-Use Endoscopy: P1-A, P1-B, P1-C, P1-D, P1-E, P2-A, P2-B, P2-C, P2-D, P2-E
Common or Usual Name:	Bronchoscope (flexible or rigid) and accessories
Classification Name:	Bronchoscope (flexible or rigid) and accessories (21 CFR 874.4680)
Product Code:	EOQ
Device Class:	Class II

Identification of the Legally Marketed Predicate Device:

Trade Name:	Vathin® Video Bronchoscope System
Classification Name:	Bronchoscope (flexible or rigid) and accessories (21 CFR 874.4680)
Product Code:	EOQ
Device Class:	Class II
Submitter/510(k) Holder:	Hunan Vathin Medical Instrument Co., Ltd.

Clearance: K191828
This predicate has not been subject to a design-related recall.

Device Description:
The Bronchoscope System consists of Single-use Bronchoscope (Model: BC12-1, BC12-2, BC20-1, BC20-2, BC22-1, BC22-2, BC22-3, BC28-1, BC28-2, BC28-3) to be introduced within the airways or tracheobronchial tree and Monitor for Single-Use Endoscopy (Model: P1-A, P1-B, P1-C, P1-D, P1-E, P2-A, P2-B, P2-C, P2-D, P2-E) for clinical image processing. The Single-use Bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The Monitor provides power and processes the images for medical electronic endoscope.

The Single-use Bronchoscope is a sterile single use flexible bronchoscope. The Monitor for Single-Use Endoscopy is a reusable monitor.

The light emitted by the LED cold light source at the distal tip of the disposable video Bronchoscope is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is captured by the CMOS image sensor. The CMOS acquisition image is controlled by the CMOS drive circuit, and the RGB video signal is output to the Monitor for Single-Use Endoscopy via the VI circuit. The Monitor receives video signals from the endoscope, processes the video signals and outputs the processed video signal. The Monitor also controls the brightness of the LEDs on the endoscope.

Indications for Use:
The Single-use Bronchoscopes have been designed to be used with the Monitor for Single-Use Endoscopy, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Bronchoscope System is for use in a hospital environment.
The Single-use Bronchoscope is a disposable device designed for use in adults.

Substantial Equivalence:
The Bronchoscope System employs the same fundamental scientific technology as its predicate device, as below table:

	Subject Device	**Predicate Device**	**Comparison**
K Number	**K231107**	**K191828**	
Model	Single-use Bronchoscope: BC12-1, BC12-2, BC20-1, BC20-2, BC22-1, BC22-2, BC22-3, BC28-1, BC28-2,	Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope: BCV1-01 BCV1-02 BCV1-C1 BCV1-C2	/

	Subject Device	Predicate Device	Comparison
K Number	**K231107**	**K191828**	
	BC28-3 Monitor for Single-Use Endoscopy : P1-A, P1-B, P1-C, P1-D, P1-E, P2-A, P2-B, P2-C, P2-D, P2-E	BCV1-H1 BCV1-H2 BCV1-K1 BCV1-K2 BCV1-M1 BCV1-M2 BCV1-O1 BCV1-O2 BCV1-S1 BCV1-S2 BCV1-U1 BCV1-U2 BCV1-W1 BCV1-W2 Vathin®VisionCenter™ I Digital Video Processor: DVP-A1	
Manufacturer	Hunan Endoso Life Technology Co., Ltd.	Hunan Vathin Medical Instrument Co., Ltd.	/
Classification Name	Bronchoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories	/
Product Code	EOQ	EOQ	/
Indications For Use:	The Single-use Bronchoscope have been designed to be used with the Monitor for Single-Use Endoscopy, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Bronchoscope System is for use in a hospital environment. The Single-use Bronchoscope is a disposable device designed for use in adults.	TheVathin®H-SteriScope™ I Single-use flexible Video Bronchoscope have been designed to be used with the Vathin® Vision Center™ I Digital Video Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree. The Vathin® Video Bronchoscope System is for use in a hospital environment.	Similar[1]
Working place/User	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	Use in a hospital environment by trained surgical physicians who are familiar with endoscopic procedures.	Same
Population	Adults	Adults	Same
Technology	The Single-use	The Flexible bronchoscope	Same

	Subject Device	Predicate Device	Comparison
K Number	**K231107**	**K191828**	
	bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the Monitor for Single-Use Endoscopy with a CMOS chip at the distal end of the endoscope and the images showing on the monitor.	is inserted through the airways and tracheobronchial tree during Bronchoscopy. Anatomical images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the images showing on a monitor.	
Physical Characteristics			
Type of Scope	Flexible	Flexible	Same
Distal end outer diameter	≤2.9mm (8.7 Fr)	≤3.1mm (9.3 Fr)	Similar[2]
Insertion Section length	600mm	600/700mm	Similar[3]
Optical Characteristics			
Type of Imager	CMOS	CMOS	Same
Direction of View	forward	forward	Same
Depth of Field	3mm~50mm	3mm~30mm	Similar[4]
Light Source	Internal LED	Internal LED	Same
Patient Contacting Materials			
General material type of main patient-contact part	Pebax, polyamide, Stainless Steel, Epoxy glue, glass, Polycarbonate, PTFE, PET	Pebax, PTFE, LCP, TPU, Fluoro elastomers, Epoxy glue, glass	Different[5]
Duration and type of contact	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	"Surface –Mucosal Membrane" with a contact duration of "Limited (< 24 hours)"	Same
Other information			
Number of Uses	Single-Use	Single-Use	Same
Sterilization	EO Sterilized, SAL 10	EO Sterilized, SAL 10^{-6}	Same

	Subject Device	Predicate Device	Comparison
K Number	**K231107**	**K191828**	
Video format inputs (Camera)	MIPI	DVI/USB	Different[6]
Storage	Yes SD Card	Yes SD Card	Same
Image/Video Capture	Yes	Yes	Same
Single use/reusable	Single-use for bronchoscope/ reusable for Monitor for Single-Use Endoscopy	Single-use for bronchoscope/ reusable for Video Processor	Same
Biocompatibility	No Cytotoxicity	No Cytotoxicity	Same
	No Irritation to Skin	No Irritation to Skin	Same
	No significant evidence of sensitization	No significant evidence of sensitization	Same
	No pyrogen	No pyrogen	Same

Analysis 1:
Only different expressions.

Analysis 2:
The thinner the outer diameter, the less damage it will cause to the patient after being inserted into the trachea; The thinner the outer diameter, the stronger the patient's comfort; The thinner the outer diameter, the easier it is for doctors to insert into the affected area of the trachea. All the performance was tested and the results met the standard requirements, this difference will not raise any issues in safety and effectiveness.

Analysis 3:
The insertion section length of subject device is covered by the predicate device.

Analysis 4:
The optical performance of the subject device was tested and the results met the ISO 8600 series, this difference will not raise any issues in safety and effectiveness.

Analysis 5:
Biocompatibility of the Single-use Bronchoscope was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1, this difference will not raise any issues in safety and effectiveness.

Analysis 6:

MIPI, DVI, and USB are all intermediate formats for data transmission, which ultimately display images on the display screen. What users see is an image, so this difference is only a difference in data transmission format, not functional performance, and does not affect safety and effectiveness.

Summary of Testing:

Summary of Non-Clinical Tests:
Electrical Safety and Electromagnetic Compatibility Summary
Electrical safety and EMC testing were conducted on the Bronchoscope System. The system complies with the IEC 60601-1 and IEC60601-2-18 for safety and the IEC 60601-1-2 for EMC.

Bench Testing Summary
The following bench tests were performed:
1. Optical performance testing according to ISO 8600 series.
2. Mechanical characteristics were performed compared with the predicate device.
3. Color feature separation and photobiological safety test.
4. Color performance (color reproduction), optical performance (resolution, depth of view and image intensity uniformity), SNR and dynamic test compared with the predicate device.

Biocompatibility Summary
Biocompatibility of the Single-use Bronchoscope 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
• Sensitization
• Intracutaneous reactivity/irritation
• Pyrogen
• Acute systemic toxicity
The Single-use Bronchoscope is considered surface – mucosal membrane contacting for duration of less than 24 hours.

Sterilization and shelf life testing
The sterilization method has been validated according to ISO11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Single-use Bronchoscope is validated.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by 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

Cybersecurity was conducted according to FDA's Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

Clinical Testing

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

Package Validation

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F88/F88M-15, ASTM F 1929-15.
Transport and shipping testing as per ASTM D4169-16.

Conclusion:

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