



April 8, 2026

MacroLux Medical Technology Co., Ltd.
Ye Linbin
Person Responsible for Regulatory Compliance
301, Bldg. 3, Namtai Inno Park
Guang Ming Ave., Shenzhen, Guangdong 518107 CHN

Re: K260420

Trade/Device Name: LoopView® Single-Use Digital Flexible Bronchoscope (B27-C, B27-CG)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: February 9, 2026
Received: February 9, 2026

Dear Ye Linbin:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

510(k) Number (if known)
K260420

Device Name
LoopView® Single-Use Digital Flexible Bronchoscope (B27-C, B27-CG)

Indications for Use (Describe)

The LoopView® 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 MACROLUX™ video processor.

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

The ViewHub® is designed to display live imaging data from compatible MACROLUX™ endoscopes.

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) #:

510(k) Summary

Prepared on: 2026-02-04

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name

MacroLux Medical Technology Co., Ltd.

Applicant Address

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Applicant Contact

Mr. Ye Linbin

Applicant Contact Email

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name

LoopView® Single-Use Digital Flexible Bronchoscope (B27-C, B27-CG)

Common Name

Bronchoscope (flexible or rigid) and accessories

Classification Name

Bronchoscope (Flexible Or Rigid)

Regulation Number

874.4680

Product Code(s)

EOQ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #

Predicate Trade Name (Primary Predicate is listed first)

Product Code

K173727

Ambu® aScope™ 4 Broncho, Ambu® aView™ Monitor

EOQ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Single-Use Digital Flexible Bronchoscope System consists of LoopView® Single-Use Digital Flexible Bronchoscope (consists of a handle with control lever, endoscope cable and access port for accessories, and a flexible body portion) and ViewHub® Video Processor with its accessories including power cable and connector cables. The LoopView® is provided sterile (sterilized by Ethylene Oxide) and intended to be single-use. The ViewHub® is a reusable multi-patient use device.

The built-in light emitting diode (LED) at the distal tip of LoopView® Single-Use Digital Flexible Bronchoscope provides a light source, the lens module captures the light signal, then the complementary metal-oxide-semiconductor (CMOS) image module converts the light signal into an electrical signal; the endoscope cable connects LoopView® to ViewHub® Video Processor, which provides power and processes video signal from the endoscope; the control lever on the handle connected to the controllable portion by a wire rope controls the bending direction and angle of the controllable portion; the instrument channel delivers water and other instruments. Suctioning of saliva and mucus from airway is possible through the suction system.

The LoopView® Single-Use Digital Flexible Bronchoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Sterilized by Ethylene Oxide (EO)
- For single-use

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The LoopView® 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 MACROLUX™ video processor.

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

The ViewHub® is designed to display live imaging data from compatible MACROLUX™ endoscopes.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of the subject device and the predicate device are the same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject and predicate devices have the same Indications for use, Population, Anatomic site, Prescription, Performance, Direction of view, Digital video technology, Illumination source, Sterilization, Biocompatibility and Electrical performance.

The subject device differs from the predicate device in Field of view, Depth of view, Working length, Maximum insertion portion width, Minimum working channel width, Deflection angle. The difference will not raise new questions on safety and effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Mechanical Performance

Mechanical characteristics were tested and include:

- Physical features
- Tensile stress testing of the joints
- Fatigue testing of the articulation section and control lever
- Insertion/extraction cycle testing of connection cable
- Bending reliability testing of connection cable
- Reliability testing of buttons

Optical Performance

Comparative testing was performed for the subject device and predicate device to support substantial equivalence, including:

- Field of view (FOV)
- Direction of view (DOV)
- Image intensity uniformity (IIU)
- Resolution
- Depth of field
- Geometric distortion
- Signal-to-noise ratio (SNR)
- Dynamic range
- Color performance

Sterility

The sterilization validation was conducted according to ISO 11135.

Biocompatibility

The biocompatibility was assessed according to FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process" and the standard ISO 10993-1. Also, the following tests were conducted based contact category of "Surface – Mucosal Membrane" with a contact duration of "Limited (< 24 hours):

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Intracutaneous reactivity (ISO 10993-23)
- Material-mediated pyrogenicity (ISO 10993-11)
- Acute systemic toxicity (ISO 10993-11)

EMC

The EMC was assessed according to FDA guidance document "Electromagnetic Compatibility (EMC) of Medical Devices" and tested according to IEC 60601-1-2 and IEC 60601-2-18.

Electrical Safety

The electrical safety was tested according to IEC 60601-1 and IEC 60601-2-18.

Photobiological Safety

The photobiological safety was tested according to IEC 62471.

The clinical data is not applicable.

The nonclinical test were conducted to demonstrate that the subject device is as safe and effective as the predicate device.