April 5, 2024

MacroLux Medical Technology Co., Ltd.
℅ Jie Yang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District,
Shenzhen, Guangdong 518067
China

Re: K233779
Trade/Device Name: LoopView® Single-Use Digital Flexible Bronchoscope (B38, B38-C, B50, B50-C, B58, B58-C), ViewHub® Video Processor (S13)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 7, 2024
Received: March 7, 2024

Dear Jie Yang:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233779

Device Name

LoopView® Single-Use Digital Flexible Bronchoscope (B38, B38-C, B50, B50-C, B58, B58-C); ViewHub® Video Processor (S13)

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) #: K233779

510(k) Summary

Prepared on: 2024-04-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	MacroLux Medical Technology Co., Ltd.
Applicant Address	301, Building 3, NamTai Inno Park In Guang Ming Avenue, Guangming Shenzhen Guangdong 518107 China
Applicant Contact Telephone	86-755-88656680
Applicant Contact	Mr. Linbin Ye
Applicant Contact Email	yelinbin@microlite.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LoopView® Single-Use Digital Flexible Bronchoscope (B38, B38-C, B50, B50-C, B58, B58-C); ViewHub® Video Processor (S13)
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 EO) and intended to be single-use. The ViewHub® is a reusable multi-patient use device.

The built-in LED at the Distal tip of the LoopView® Single-Use Digital Flexible Bronchoscope provides a light source, the lens module captures the light signal, then the CMOS module converts the light signal into an electrical signal; the endoscope cable connects the LoopView® to the ViewHub®, 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 ViewHub® Video Processor is a video imaging system that receives video signals from the connected endoscope, controls the light at the endoscope tip and outputs this signal including a graphical user interface to a connected external video monitor.

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
- For single-use

The ViewHub® Video Processor has the following physical and performance characteristics:
- Snapshot, white balance, zoom and HD video output
- supports HDMI video output formats
- Touch Panel
- Reusable

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 proposed device has the same technological characteristics including technology, parameters for bronchoscope(including direction of view, working length, maximum insertion portion width,deflection angle and sterility) and parameters for processor(including illumination source, brightness control, white balance, image/video capture and external monitor) as the predicate device.
The technological differences exist between the proposed and predicate device on aspects including FOV(proposed/predicate device:125°/85°), depth of view(proposed/predicate device:3-100mm/6-50mm) and Minimum channel width(proposed/predicate device:B38,B38 -C: ≥Ø 2.0mm; B50,B50 -C:≥Ø 2.2mm; B58, B58 -C: ≥Ø 2.8mm/Slim: 1.2 mm; Regular: 2.0 mm; Large: 2.6 mm).The differences will not raise new questions on safety and effectiveness of the proposed device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Biocompatibility testing
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
-Intradermal reactivity
The Single-use Bronchoscope is considered surface – mucosal membrane contacting for a duration of less than 24 hours.

Sterilization and shelf life testing
The Single-use Bronchoscope is provided sterile and its shelf-life is 3 years.
Sterilization Process has been validated accordance with ISO 11135:2014.
EO/ECH residual test was performed according to ISO 10993-7:2008.
The shelf life is determined by accelerated aging test according to ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and ASTM F1886/F1886M-16, ASTM F88/F88M-15, ASTM F 1929-15.

Electrical safety and electromagnetic compatibility (EMC)
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.

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, "Content of Premarket Submissions for Device Software Functions."

Bench performance testing

1.Optical performance testing according to ISO 8600 series.
2.Color performance, geometric distortion, optical performance
(resolution, depth of field and image intensity uniformity), and SNR and dynamic range tests compared with the predicate device.
3. Mechanical testing including physical features, accessories compatibility, suction and bending testing.

It is concluded form the nonclinical tests that demonstrate that the subject devices are as safe, as effective, and performs as well as the legally marketed predicate device identified above.