July 20, 2026

MacroLux Medical Technology Co., Ltd.
Ye Linbin
Regulatory Compliance
301, Bldg. 3, Namtai Inno Park In Guang Ming Ave.,
Shenzhen, Guanfdong 518107
CHINA

Re: K260516
Trade/Device Name: BubbleView Single-Use Digital Flexible Cystoscope
(C38-CS, C38-CRS, C50-C, C50-CR, C50-CB, C50-CBR)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB, FAJ
Dated: July 6, 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

510(k) Number *(if known)*
K260516

Device Name
BubbleView Single-Use Digital Flexible Cystoscope (C38-CS, C38-CRS, C50-C, C50-CR, C50-CB, C50-CBR)

Indications for Use *(Describe)*
The BubbleView Single-Use Digital Flexible Cystoscope is a sterile, single-use, flexible endoscope intended to be used for endoscopy and endoscopic surgery within urinary tract and interior of the kidney. The BubbleView is intended to provide visualization via ViewHub video processor and can be used with endoscopic accessories.
BubbleView is intended for use in a hospital environment or medical office environment.
BubbleView is 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) #: K260516

510(k) Summary

Prepared on: 2026-07-06

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 Shenzhen Guanfdong 518107 China
Applicant Contact Telephone	+8613430891962
Applicant Contact	Mr. Ye Linbin
Applicant Contact Email	yelinbin@microlite.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BubbleView Single-Use Digital Flexible Cystoscope (C38-CS, C38-CRS, C50-C, C50-CR, C50-CB, C50-CBR)
Common Name	Endoscope and accessories
Classification Name	Ureteroscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FGB, FAJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172098	Medical Video Endoscope System	FGB

Device Description Summary

21 CFR 807.92(a)(4)

The BubbleView Single-Use Digital Flexible Cystoscope consists of a handle with control lever, endoscope cable and access port for accessories, and a flexible body portion. The BubbleView is provided sterile (sterilized by EO) and intended to be single-use.
The built-in LED at the Distal tip of the BubbleView Single-Use Digital Flexible Cystoscope 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 BubbleView 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; the suction connector allows for connection of suction tubing.

The BubbleView is intended to used combined with ViewHub Video Processor to perform its intended function and the ViewHub has been 510(k) cleared in the K240283.

The BubbleView Single-Use Digital Flexible Cystoscope 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

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The BubbleView Single-Use Digital Flexible Cystoscope is a sterile, single-use, flexible endoscope intended to be used for endoscopy and endoscopic surgery within urinary tract and interior of the kidney. The BubbleView is intended to provide visualization via ViewHub video processor and can be used with endoscopic accessories.
BubbleView is intended for use in a hospital environment or medical office environment.
BubbleView is designed for use in adults.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the subject device and the predicate devices 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.