June 10, 2024

MacroLux Medical Technology Co., Ltd.
Linbin Ye
Person Responsible for Regulatory Compliance
301, Building 3, NamTai Inno Park In Guang Ming Avenue
Guangming
Shenzhen, Guangdong
CHINA

Re: K240283
Trade/Device Name: BubbleView™ Single-Use Digital Flexible Cystoscope (C50-C, C50-CR, C50-CB, C50-CBR); ViewHub® Video Processor (S13, S13-T, S13-N, S13-S)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Received: May 14, 2024

Dear Linbin Ye:

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,

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.

Submission Number *(if known)*

K240283

Device Name

BubbleView™ Single-Use Digital Flexible Cystoscope (C50-C, C50-CR, C50-CB, C50-CBR); ViewHub® Video Processor (S13, S13-T, S13-N, S13-S)

Indications for Use *(Describe)*

The BubbleView™ Single-Use Digital Flexible Cystoscope is a sterile, single-use, flexible endoscope intended to be used for endoscopic access to and examination of the lower urinary tract. 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.
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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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 Shenzhen China
Applicant Contact Telephone	+8613430891962
Applicant Contact	Mr. Linbin Ye
Applicant Contact Email	yelinbin@microlite.cn

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BubbleView™ Single-Use Digital Flexible Cystoscope (C50-C, C50-CR, C50-CB, C50-CBR); ViewHub® Video Processor (S13, S13-T, S13-N, S13-S)
Common Name	Endoscope and accessories
Classification Name	Cystoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FAJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222602	Pusen Single Use Flexible Video Cystoscope System (Single Use Flexible Video Cystoscope: PC200-AS, PC200-AR, PC200-S and PC200-R; HD Medical Video Endoscope Image Processor: PV300)	FAJ

Device Description Summary

21 CFR 807.92(a)(4)

The Single-Use Digital Flexible Cystoscope System consists of 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) and ViewHub® Video Processor with itsaccessories including power cable and connector cables. The BubbleView™ 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 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 handleconnected 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 ViewHub® Video Processor is a video imaging system that receives video signals from the connected endoscope, controls the lightat the endoscope tip and outputs this signal including a graphical user interface to a connected external video monitor.

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

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 BubbleView™ Single-Use Digital Flexible Cystoscope is a sterile, single-use, flexible endoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The BubbleView™ is intended to provide visualization via ViewHub® video processorand 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.
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, type of scope, scope reusability, anatomical site, working length, type of image sensor, illumination source, sterilization, environment of use, energy source, applied standards related toperformance, biocompatibility and electrical performance. The subject device differs from the predicate in maximum insertion portion width, minimum instrument channel width, up/down deflection, direction of view, field of view, depth of field and Suction. These differences do not raise different questions of safety and effectiveness as compared to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Mechanical Performance
Mechanical characteristics were tested and include:
- Tensile stress testing of the joints
- Fatigue testing of articulation section
- Reliability test of control lever
- Performance tests of irrigation plug and clamp column
- Times of connection cable being inserted and pulled out
- Reliability test of handle button
- Bending times of the connection cable

Optical Performance
Comparative testing was performed for the subject device and predicate device to support substantial equivalence, including:
- Field of view (FOV)
- Resolution
- Depth of field (DOF)
- Signal-to-noise ratio (SNR)
- Dynamic range
- Image intensity uniformity (IIU)
- Geometric distortion
- Color performance

Not applicable.

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