January 11, 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, 518107
CHINA

Re: K231774

Trade/Device Name: CoralView® Single-use Digital Flexible Ureteroscope (U10);
CoralView® Single-use Digital Flexible Ureteroscope (U10-B);
CoralView® Single-use Digital Flexible Ureteroscope (U10-BR);
CoralView® Single-use Digital Flexible Ureteroscope (U20);
CoralView® Single-use Digital Flexible Ureteroscope (U20-B);
CoralView® Single-use Digital Flexible Ureteroscope (U20-BR)

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: August 4, 2023
Received: December 8, 2023

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 J. Antonino -S

Mark 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231774

Device Name

CoralView® Single-use Digital Flexible Ureteroscope (U10);
CoralView® Single-use Digital Flexible Ureteroscope (U10-B);
CoralView® Single-use Digital Flexible Ureteroscope (U10-BR);
CoralView® Single-use Digital Flexible Ureteroscope (U20);
CoralView® Single-use Digital Flexible Ureteroscope (U20-B);
CoralView® Single-use Digital Flexible Ureteroscope (U20-BR);
ViewHub® Video Processor

Indications for Use *(Describe)*

The device is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

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.

510(k) #: K231774	510(k) Summary	Prepared on: 2023-12-12

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 518107 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	CoralView® Single-use Digital Flexible Ureteroscope (U10); CoralView® Single-use Digital Flexible Ureteroscope (U10-B); CoralView® Single-use Digital Flexible Ureteroscope (U10-BR); CoralView® Single-use Digital Flexible Ureteroscope (U20); CoralView® Single-use Digital Flexible Ureteroscope (U20-B); CoralView® Single-use Digital Flexible Ureteroscope (U20-BR); ViewHub® Video Processor
Common Name	Endoscope and accessories
Classification Name	Ureteroscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code	FGB

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 Single-Use Digital Flexible Ureteroscope System consists of CoralView® Single-Use Digital Flexible Ureteroscope (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 power cable and connector cables. The CoralView® 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 CoralView® Single-Use Digital Flexible Ureteroscope 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 CoralView® 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 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 CoralView® Single-use Digital Flexible Ureteroscope 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, DVI, CVBS and S-VIDEO video output formats
 Touch Panel
 Reusable.

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

The device is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

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

The device has same indications for use in comparison to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices have the same indications for use, type of image sensor, type of scope, direction of view, field of view, depth of field, illumination source, sterilization method and energy source. The subject device differs from the predicate in distal end outer diameter, maximum insertion portion width, insertion section length, maximum deflection angle and patient-contacting materials. 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)

Biocompatibility testing
Biocompatibility of the Single-Use Flexible Ureteroscope was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "breached or compromised surface" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity, Irritation, Sensitization, Pyrogenicity and Acute systemic toxicity. All evaluation acceptance criteria were met.

Electrical Safety and Electromagnetic Compatibility Summary
The electrical safety and EMC data included in the submission meets the following FDA recognized standards:
•AAMI/ANSI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
•ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]
•IEC 60601-2-18: Edition 3.0 2009-08

Mechanical Performance
Mechanical characteristics were tested and include:
- Articulation section fatigue testing
- Control lever reliability test
- Tensile stress testing of the joints
- Performance tests for irrigation plug

Photobiological safety
The LEDs in submitted Ureteroscope were tested according to IEC 62471:2006.

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)
- Unit relative distortion
- Color performance

Software and Cybersecurity

The system complies with the following standard and guidance:

- ANSI AAMI IEC 62304:2006/A1:2016
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Nonclinical tests demonstrated that the CoralView® Single-use Digital Flexible Ureteroscope is as safe and effective as the predicate device.