August 16, 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: K240978
Trade/Device Name: SeleneView® Single-Use Digital Hysteroscope
(HC29, HC29-G, HC35, HC35-G, HO35, HO35-G, HO42, HO42-G)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: Class II
Product Code: HIH
Dated: April 7, 2024
Received: August 5, 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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
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)*
K240978

Device Name
SeleneView® Single-Use Digital Hysteroscope (HC29, HC29-G, HC35, HC35-G, HO35, HO35-G, HO42, HO42-G)

Indications for Use *(Describe)*
The SeleneView® (model: HC29, HC29-G, HC35, HC35-G) is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures.
The SeleneView® (model: HO35, HO35-G, HO42, HO42-G) is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures.
SeleneView® is intended for use in professional healthcare facility environments such as hospitals and clinics.
SeleneView® 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K240978

510(k) Summary

Prepared on: 2024-08-16

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

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SeleneView® Single-Use Digital Hysteroscope (HC29, HC29-G, HC35, HC35-G, HO35, HO35-G, HO42, HO42-G)
Common Name	Hysteroscope and accessories
Classification Name	Hysteroscope (And Accessories)
Regulation Number	884.1690

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232003	Single-Use Video Hysteroscope: RP-G-C24, RP-G-C0101	HIH

Device Description Summary

21 CFR 807.92(a)(4)

SeleneView® Single-Use Digital Hysteroscope consists of a handle, insertion portion and endoscope cable. SeleneView® is provided sterile (sterilized by ethylene oxide [EO]) and intended to be single-use.
The built-in light emitting diode (LED) at the distal tip of SeleneView® Single-Use Digital Hysteroscope 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 SeleneView® to ViewHub® Video Processor, which provides power and processes video signal from the endoscope.
The SeleneView® is intended to be used combined with ViewHub® Video Processor to perform its intended function and the ViewHub® has been 510(k) cleared in K233779.

SeleneView® Single-Use Digital Hysteroscope has the following physical and performance characteristics:
- 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 SeleneView® (model: HC29, HC29-G, HC35, HC35-G) is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures.
The SeleneView® (model: HO35, HO35-G, HO42, HO42-G) is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures.
SeleneView® is intended for use in professional healthcare facility environments such as hospitals and clinics.
SeleneView® 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 device are the same.

Technological Comparison 21 CFR 807.92(a)(6)

Item	Subject device	Predicate device (K232003)
Indications for use	The SeleneView® (model: HC29, HC29-G, HC35, HC35-G) is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures. The SeleneView® (model: HO35, HO35-G, HO42, HO42-G) is used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures. SeleneView® is intended for use in professional healthcare facility environments such as hospitals and clinics. SeleneView® is designed for use in adults.	The Single-Use Video Hysteroscope is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures. The device is suitable for professional healthcare facility environments such as hospitals and clinics.
Population	Adult	Adult
Prescription/over-the-counter use	Prescription	Prescription
Route of advancement	Advanced to uterine cavity via the cervical canal	Advanced to uterine cavity via the cervical canal
Maximum insertion portion width	HC29/HC29-G: 2.9mm; HC35/HC35-G: 3.85mm; HO35/HO35-G: 3.8mm; HO42/HO42-G: 4.3mm	RP-G-C24: 5.5mm; RP-G-C0101: 4.8mm
Minimum working channel width	HC29/HC29-G: none; HC35/HC35-G: none; HO35/HO35-G: ≥1.8mm; HO42/HO42-G: ≥2.0mm	RP-G-C24: 2.3mm; RP-G-C0101: 2.0mm
Working length	220 mm	270 mm
Type of image sensor	CMOS	CMOS
Image resolution	HC29/HC29-G/HO35/HO35-G: 400*400 pixels HC35/HC35-G/HO42/HO42-G: 1280*720 pixels	160,000 pixels
Direction of view	15°	RP-G-C24: 22° RP-G-C0101: 30°
Field of view	HC29/HC29-G/HO35/HO35-G: 120°; HC35/HC35-G/HO42/HO42-G: 140°	120°
Depth of field	3mm~100mm	RP-G-C24: 3~50 mm RP-G-C0101: 5~50 mm
Illumination source	LED	LED
Image transmission	The images are transmitted through the endoscope with a CMOS image module at the distal end and video processor.	The images are transmitted through the endoscope with a CMOS image module at the distal end and video processor.
Capture still images or video images during the procedure	Capture images or video during procedure by the video processor	Capture images or video during procedure by the video processor
Sterilization	The Hysteroscope is sterile after sterilization with ethylene oxide (EO)	The Hysteroscope is sterile following exposure to ethylene oxide (EO)
Performance	Comply with ISO 8600	Comply with ISO 8600
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1
Electrical performance	Comply with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-18	Comply with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-18

The subject and predicate devices have the same Indications for use, Population, Prescription, Route of advancement, Illumination source, Image transmission, Capture still images or video images during the procedure, Sterilization, Performance, Biocompatibility and Electrical performance. The subject device differs from the predicate in Maximum insertion portion width, Minimum working channel width, Working length, Image resolution, Direction of view, Field of view and Depth of field. 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
- Performance tests for Luer interface (per ISO 80369-7:2021)
- Sealing performance of working channel
- Performance tests for inlet/outlet channels and flow control valve
- Strength and stiffness of insertion portion

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

Sterility
The sterilization validation was conducted according to ISO 11135:2014/A1:2018.

Biocompatibility
The biocompatibility was assessed according to 2023 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.
The following tests were conducted based contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours):
- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Intracutaneous reactivity (ISO 10993-23:2021)
- Material-mediated pyrogenicity (ISO 10993-11:2017)
- Acute systemic toxicity (ISO 10993-11:2017)

EMC
The EMC was assessed according to the 2022 FDA guidance document “Electromagnetic Compatibility (EMC) of Medical Devices” and tested according to IEC 60601-1-2:2020 and IEC 60601-2-18:2009.

Electrical Safety
The electrical safety was tested according to IEC 60601-1:2020 and IEC 60601-2-18:2009.

Photobiological Safety
The photobiological safety was tested according to IEC 62471:2006.

It is concluded form the nonclinical tests that the subject devices are as safe, as effective, and perform as well as thelegally marketed predicate device identified above to support a substantial equivalence determination.