October 6, 2023

Medimaging Integrated Solution Inc. (MiiS)
Luu Hsu
Official Correspondent
3F., No. 24-2, Industry E. Rd. IV, Hsinchu Science Park
Hsinchu, Taiwan 30077
China

Re: K223926
Trade/Device Name: Cystoscope: VersaVue™ Single-Use Flexible Cystoscope
Tablet: VersaVue™ Tablet
Video Box: VersaVue™ Video Box
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ
Dated: September 8, 2023
Received: September 8, 2023

Dear Luu Hsu:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223926

Device Name
Cystoscope: VersaVue™ Single-Use Flexible Cystoscope
Tablet: VersaVue™ Tablet
Video Box: VersaVue™ Video Box

Indications for Use *(Describe)*
The VersaVue™ Single-Use Flexible Cystoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system (VersaVue™ Tablet OR VersaVue™ Video Box). The device provides endoscopic procedure and surgical treatment within the lower urinary tract.

The Cystoscope is intended to provide visualization via displaying unit.

The Cystoscope is intended for use in a hospital environment or medical office environment. It 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.

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510(k) Summary

Prepared: September 27, 2023

Submitter/Owner's Name/ Address Medimaging Integrated Solution Inc. (MiiS)
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Device Identification:

Trade/Device Name: Cystoscope: VersaVue™ Single-Use Flexible Cystoscope
Tablet: VersaVue™ Tablet
Video Box: VersaVue™ Video Box
Common Name: Cystoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FAJ

Predicate Device:

K193095
Trade/Device Name: Ambu aScope 4 Cysto
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FAJ

Description of Device:

VersaVue™ Single-Use Flexible Cystoscope is a single-use, flexible, sterile cystoscope. The illumination LED locate at the tip of the distal end. There is a bending section near the region of distal end, which manipulated by the control lever on the handle part, can provide visions with more than one direction for the users. The signal captured was then transmitted to the cable-connected display system (VersaVue™ Tablet OR VersaVue™ Video Box). The working channel provide access for accessories to conduct surgical process.

VersaVue™ Tablet is a tablet. The live imaging or snapshot will present directly on the tablet.

VersaVue™ Video Box is a standalone imaging transfer system, it can be connected to computer to project live imaging. The function of VersaVue™ Single-Use Flexible Cystoscope is to provide live imaging of the lower urinary tract, including tissue appearance recording, snapshot, vertical flip and horizontal flip. Table 1 below includes a summary of the technical information used in the substantial equivalence comparison.

Indications for Use (IFU):

The VersaVue™ Single-Use Flexible Cystoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system (VersaVue™ Tablet OR VersaVue™ Video Box). The device provides endoscopic procedure and surgical treatment within the lower urinary tract.

The Cystoscope is intended to provide visualization via displaying unit.

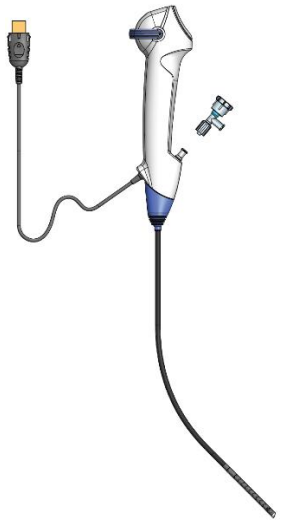
The Cystoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.

Substantial Equivalence Summary

Below is a summary table comparing the IFUs and key technological characteristics between the subject and the predicate devices.

Device	K223926	K193095
Model name	Cystoscope: VersaVue™ Single-Use Flexible Cystoscope Tablet: VersaVue™ Tablet Video Box: VersaVue™ Video Box	Ambu aScope 4 Cysto
Product code & Classification	21 CFR 876.1500, FAJ Class II	21 CFR 876.1500, FAJ Class II
Intended use	The VersaVue™ Single-Use Flexible Cystoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system (VersaVue™ Tablet OR VersaVue™ Video Box). The device provides endoscopic procedure and surgical treatment within the lower urinary tract. The Cystoscope is intended to provide visualization via displaying unit.	The aScope 4 Cysto is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The aScope 4 Cysto is intended to provide visualization via the reusable Ambu Displaying Unit and can be used with endoscopic accessories and instruments. The aScope 4 Cysto is intended for use in a hospital environment

	The Cystoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.	or medical office environment. The aScope 4 Cysto is designed for use for adult patients requiring cystoscopy.
Lens Specification	FOV: 120° DOV: 0° DOF: 3-50 mm	FOV: 120° DOV: 0° DOF: 3-100 mm
Mechanical Specification	Bending angle: Up: 220°/Down: 130° Working length: 380 mm Distal end diameter: 5.5 mm Working channel diameter: 2.33 mm	Bending angle: Up: 210°/Down: 120° Working length: 390 mm Distal end diameter: 5.4 mm Working channel diameter: 2.2 mm
EMC	IEC 60601-1-2	IEC 60601-1-2
Safety	IEC 60601-1 IEC 60601-2-18	IEC 60601-1 IEC 60601-2-18
Bench test	ISO 8600-1 ISO 8600-3 ISO 8600-4	ISO 8600-1 ISO 8600-3 ISO 8600-4
Sterilization	EO Sterilization	EO Sterilization
Materials	Acroylonitrile butadiene styrene (ABS), Polyurethane, polycarbonate, polyethylene, silicon rubber, UV-curing resin, thermoplastic elastomer (Pebax)	Methyl Acrylonitrile Butadiene Styrene (MABS), Polyurethane, polypropylene, Polycarbonate, Polyoxymethylene, Polyvinylchloride
LED Light source	At distal tip	At distal tip

Appearance		

Substantial Equivalence Discussion

Similarities:

- VersaVue™ Single-Use Flexible Cystoscope and the predicate device, Ambu aScope 4 Cysto (K193095), have the same intended use and similar specifications in field of view, direction of view, depth of field, bending angle, working length, outer diameter, working channel diameter, sterilization method, light source location and appearance.

Differences:

- The differences lie in the optical specification (depth of field), bending angle, outer diameter of the insertion tube, working length and working channel diameter. Differences about most of these features are not more than 10%. Although the difference becomes bigger in the feature of depth of field, the usability test proves that image performance and the usability of the device are both acceptable during clinical use. Additionally, the materials of the subject device are different. The materials were tested. Thus, it is considered that there is no significance difference occurs between VersaVue™ Single-Use Flexible Cystoscope with its predicate devices.

Nonclinical Tests

The following tests have been performed in support of the substantial equivalence determination:

- Electrical safety per IEC/EN 60601-1:2005/2006+A1:2012/2013+A2:2020/2021.
- Electromagnetic Compatibility per IEC/EN 60601-1-2:2014/2015+A1:2020/2021

- Sterilization Validation per ISO 11135:2014 and ISO 11737-1:2019
- Package Integrity per ISO 11607-1:2019
- EO/ECH Residue per ISO 10993-7:2008
- Transportation test per ASTM D4169-22
- Aging test per ASTM F1980-16
- ISO 14971:2019, EN ISO 14971:2019 and MDR 2017/745 for risk management.
- Light hazards per IEC 62471:2006
- Biocompatibility:
    - Cytotoxicity test per ISO 10993-5:2009
    - Sensitization and Irritation test per ISO 10993-10:2021
    - Material mediated pyrogenicity and systemic toxicity test per ISO 10993-11:2017
- Optical and Color performance testing:
    - Field of view and direction of view
    - Resolution
    - Depth of field
    - Geometric distortion
    - Image intensity uniformity (IIU)
    - Noise and dynamic range
    - Color performance

Clinical Tests

No clinical studies were performed.

Optical Radiation Safety Assessment

The VersaVue™ Single-Use Flexible Cystoscope was tested according to ISO 62471:2006 to determine acceptable light safety limits for both the illumination. The test results demonstrate the VersaVue™ Single-Use Flexible Cystoscope meets the requirements of the standard.

Conclusion

Substantial equivalence comparison and bench performance tests support the conclusion of substantial equivalence of VersaVue™ Single-Use Flexible Cystoscope to the predicate devices Ambu aScope 4 Cysto (K193095).