August 22, 2024

LiNA Medical Aps
% Richelle Helman
Senior Director, Regulatory
MEDIcept, Inc.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K240227
Trade/Device Name: LiNA CystoVu™ HD (CYV-100-5; CYV-101-5);
LiNA ScopeVu™ (SCP-100-1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Received: July 26, 2024

Dear Richelle Helman:

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,

Sharon M. Andrews -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)*

K240227

Device Name

LiNA CystoVu™ HD (CYV-100-5; CYV-101-5);
LiNA ScopeVu™ (SCP-100-1)

Indications for Use *(Describe)*

The LiNA CystoVu HD is intended for use in visualization via LiNA displaying unit of adult male and female urethra and bladder cavity during diagnostic and therapeutic cystoscopy procedures. It is intended for hospital- or medical office environment use and is operated by medical professionals.

The LiNA ScopeVu is intended for visualization from compatible LiNA endoscopes for female and male patients of all ages during diagnostic and therapeutic endoscopy procedures. It is intended for hospital- or medical office environment use and is operated by medical professionals.

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

I. SUBMITTER

510(k) Holder: LiNA Medical ApS
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Contact Person: Richelle Helman
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Date Prepared: August 20, 2024

II. DEVICE

Name of Device: LiNA CystoVu™ HD (CYV-100-5, CYV-101-5) and LiNA ScopeVu™ (SCP-100-1)
Common Name: Cystoscope And Accessories, Flexible/Rigid
Classification Name: Endoscope and accessories (21 CFR 876.1500)
Regulatory Class: Class II
Product Code: FAJ

III. PREDICATE DEVICE

K193095 Ambu® aScope™ 4 Cysto
The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The LiNA CystoVu™ HD is a sterile, single-use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. Visualization will be achieved by LiNA ScopeVu™ full HD display and light source. The LiNA CystoVu™ HD is intended to be used with a reusable LiNA ScopeVu™ to visualize the urethra and the bladder. The LiNA CystoVu™ HD can be operated by the left or right hand. The optical module in the distal tip consists of a camera housing containing camera and LED light sources.

V. INTENDED USE/INDICATIONS FOR USE

The LiNA CystoVu HD is intended for use in visualization via LiNA displaying unit of adult male and female urethra and bladder cavity during diagnostic and therapeutic cystoscopy procedures. It is intended for hospital- or medical office environment use and is operated by medical professionals.

The LiNA ScopeVu is intended for visualization from compatible LiNA endoscopes for female and male patients of all ages during diagnostic and therapeutic endoscopy procedures. It is intended for hospital- or medical office environment use and is operated by medical professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate Ambu aScope 4 Cysto and the subject LiNA CystoVu HD and the LiNA ScopeVu is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences. (Table 1) The technological characteristic similarities and differences rationale demonstrates that the LiNA CystoVu HD and the LiNA ScopeVu are safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate Ambu aScope 4 Cysto.

Table 1. Substantial Equivalence for the Subject LiNA CystoVu HD and Predicate Ambu aScope 4 Cysto

Characteristic	**Subject Device LiNA CystoVu HD LiNA Medical**	**Predicate Device Ambu aScope 4 Cysto Ambu Inc. (K193095)**	**Equivalence Comparison**
Regulatory Class	Class II	Class II	**Same**
Regulatory Number	876.1500	876.1500	**Same**
Regulation Name	Endoscope and Accessories	Endoscope and Accessories	**Same**
Product Code	FAJ	FAJ	**Same**
Device Definition	Cystoscope and Accessories, Flexible/Rigid	Cystoscope and Accessories, Flexible/Rigid	**Same**
Intended Use/ Indications for Use	The LiNA CystoVu HD is intended for use in visualization via LiNA displaying unit of adult male and female urethra and bladder cavity during diagnostic and therapeutic cystoscopy procedures. It is	Ambu® 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 Ambu® aScope™ 4 Cysto is intended to	**Same**

Characteristic	Subject Device LiNA CystoVu HD LiNA Medical	Predicate Device Ambu aScope 4 Cysto Ambu Inc. (K193095)	Equivalence Comparison
	intended for hospital- or medical office environment use and is operated by medical professionals.	provide visualization via Ambu® displaying unit and can be used with endoscopic accessories. Ambu® aScope™ 4 Cysto is intended for use in a hospital environment or medical office environment. Ambu® aScope™ 4 Cysto is designed for use in adults.	
Use Population	Adults	Adults	**Same**
Use Environment	Professional Healthcare Facility Environment	Professional Healthcare Facility Environment	**Same**
Operating Principle	The camera is placed at the distal tip of the flexible catheter. The working channel (used for irrigation and route for surgical instruments), the wires from the camera and the optical fibers (for the illumination of the organs) are all running inside the flexible catheter. The active tip can be articulated by the user by using the lever on the handle.	The camera is placed at the distal tip of the flexible catheter. The working channel (used for irrigation and route for surgical instruments), the wires from the camera and for the LED's (for the illumination of the organs) are all running inside the flexible catheter. The active tip can be articulated by the user by using the lever on the handle.	**Same**
Endoscope feature	Flexible with a maneuverable tip.	Flexible with a maneuverable tip.	**Same**
Handle	It has a control button giving the operator the ability to maneuver the endoscope tip up and down.	It has a control button giving the operator the ability to maneuver the endoscope tip up and down.	**Same**
Insertion Portion:			

Characteristic	Subject Device LiNA CystoVu HD LiNA Medical	Predicate Device Ambu aScope 4 Cysto Ambu Inc. (K193095)	Equivalence Comparison
Articulation angle	210° up and 210° down	210° up and 120° down	**Up articulation, same. Down articulation, different**
IP Diameter	5.0 mm	5.4 mm	**Same**
Distal End Diameter	2.3 mm	5.4 mm	**Different**
Max. Diameter	5.6 mm	6.0 mm	**Same**
Working Length	390 mm	390 mm	**Same**
Working Channel	Width: 2.5mm	Width: 2.2 mm	**Same**
Working Channel Access	Graspers and other instrumentation.	Graspers and other instrumentation.	**Same**
Irrigation	Yes	Yes	**Same**
Camera location	At the distal tip to provide an image on a monitor.	At the distal tip to provide an image on a monitor.	**Same**
Illumination	Provided at the distal tip.	Provided at the distal tip.	**Same**
Light Source	LED	LED	**Same**
Connection	It is connected to a monitor by a cable.	It is connected to a monitor by a cable.	**Same**
Distal Tip Diameter	5.4 mm	5.4mm	**Same**
Insertion Cord	Flexible	Flexible	**Same**
Use Frequency	CystoVu: single use	Cysto: single use	**Same**
Sterilization	Ethylene Oxide	Ethylene Oxide	**Same**

VII. PERFORMANCE DATA

Non-clinical performance testing was conducted in order to demonstrate that the LiNA CystoVu HD and LiNA ScopeVu perform according to their requirements and specifications.

- Functional and performance testing were conducted to provide confirmation that mechanical instrumentation satisfies the functional performance requirements including force/bending/tensile stress and stress cracking and irrigation flow testing.
- Optical performance testing was conducted in accordance with the ISO 8600 series.
- Color performance, geometric distortion, optical performance (field of view, resolution, depth of field and image intensity uniformity), SNR and dynamic range, image frame frequency and system delay test compared with the predicate device.
- Electrical safety and EMC testing were conducted. The system complies with IEC 60601-1 and IEC 60601-2-18 for safety and IEC 60601-1-2 for EMC.

- Software verification and validation were conducted as required by IEC 62304 and documentation was provided as recommended by FDA Guidance "Content of Premarket Submissions for Device Software Functions".
- Biocompatibility testing was conducted in accordance with the ISO 10993 series. All tests indicated the patient contact materials were biocompatible.
- Sterilization process has been validated in accordance with ISO 11135 to an SAL of 10^{-6}.
- Human factors testing was conducted in compliance with the requirements of IEC 62366, IEC 60601-1-6 and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". Test participants representing the intended users of the device were included in the human factors validation testing. Observational data as well as interview data were recorded. The observation of participant performance and the assessment of their understanding of essential information through the interview confirmed that the design of the device is safe and effective for the intended users, uses and use environments.

The results demonstrated that the LiNA CystoVu™ HD and LiNA ScopeVu™ perform according to their specifications and function as intended.

Clinical data was not used to support substantial equivalence of the subject device to the predicate device.

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, performance data and comparison to the predicate device it was shown that the LiNA CystoVu™ HD and LiNA ScopeVu™ is substantial equivalent to the predicate Ambu® aScope™ 4 Cysto.