January 4, 2018

LiNA Medical ApS
% Jennifer Tribbett
Director of Regulatory Affairs
Emergo Global Consulting, LLC
2500 Bee Cave Rd. Bldg. 1, Suite 300
Austin, TX 78746

Re: K171113
Trade/Device Name: LiNA OperaScope
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: November 22, 2017
Received: November 30, 2017

Dear Jennifer Tribbett:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171113

Device Name
LiNA OperaScope

Indications for Use *(Describe)*

The LiNA OperaScope is intended for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures.

The types of procedures where the OperaScope could offer visualization include:

- Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram;
- Assessment of infertility and pregnancy wastage;
- Confirmation of the presence of intrauterine foreign body;
- Assist in locating submucosal fibroids and polyps targeted for removal;
- Provide visual guidance during directed biopsy, submucosal myomectomy, transection of intrauterine adhesions and septa.

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.

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510(k) Summary

LiNA OperaScope

K171113

1. Submission Sponsor

LiNA Medical ApS

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2. Submission Correspondent

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Contact: Jennifer Tribbett

Title: Director of Regulatory Affairs and Quality Assurance

Office Phone: (512) 327.9997

3. Date Prepared

January 2, 2018

4. Device Identification

Trade/Proprietary Name: LiNA OperaScope

Common/Usual Name: Hysteroscope

Classification Name: Hysteroscope and Accessories

Regulation Number: 884.1690

Product Code: HIH, Hysteroscope and Accessories

Device Class: Class II

Classification Panel: Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

- K132384 (Primary Predicate): U-Scope 8000 System with HSC+EMB Cannula
- K092278: Gyrus ACMI Invisio Digital Hysteroscope System

LiNA Medical performed a search of FDA's Medical Device Recall data base and did not discover any recalls for these legally marketed predicate devices.

6. Indication for Use Statement

The LiNA OperaScope is intended for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures.

The types of procedures where the OperaScope could offer visualization include:

• Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram;

• Assessment of Infertility and pregnancy wastage;

• Confirmation of the presence of intrauterine foreign body;

• Assist in locating submucosal fibroids and polyps targeted for removal;

• Provide visual guidance during directed biopsy, submucosal myomectomy, transection of intrauterine adhesions and septa.

Table A compares the OperaScope to the predicate devices with respect to the Indications for Use.

The OperaScope Indications for Use statement is basically a combination of the two predicate device Indications for Use. Although the wording is slightly different between the subject and predicate devices, the overall intent is the same and does not expand the clinical use of the subject device.

Table A – Comparison of Indications for Use

Manufacturer	LiNA Medical ApS	EndoSee Corporation	Gyrus ACMI Inc.
Trade Name	**OperaScope**	**U-Scope 8000 HSC+EMB Cannula**	**Gyrus ACMI Invisio Digital Hysteroscope System**
510(k) Number	K171113	K132384	K092278
Indications for Use	The LiNA OperaScope is intended for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures. The types of procedures where the OperaScope could offer visualization include: • Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram; • Assessment of Infertility and pregnancy wastage; • Confirmation of the presence of intrauterine foreign body; • Assist in locating submucosal fibroids and polyps targeted for removal; • Provide visual guidance during directed biopsy, submucosal myomectomy, transection of intrauterine adhesions and septa.	Intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy). The sample is used for cytologic and histologic diagnosis. Generally recognized indications for diagnostic hysteroscopy include: abnormal bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea and pelvic pain.	Intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. Diagnostic Hysteroscopy: • Abnormal uterine bleeding • Infertility & pregnancy wastage • Evaluation of abnormal hysterosalpingogram • Intrauterine foreign body • Amenorrhea • Pelvic pain Operative Hysteroscopy: • Directed biopsy • Removal of fibroids and polyps • Transection of intrauterine adhesions • Transection intrauterine septa

7. Device Description

The LiNA OperaScope is a handheld, battery-operated portable hysteroscope which allows direct viewing of the cervical canal and uterine cavity via the on-board LCD display. If the user wants to capture images and/or record video sequences utilizing a USB stick, a Recording Module is available, which connects to the device via the HDMI cable. The OperaScope can also be connected to an external monitor via the HDMI cable. External monitors are not provided by LiNA Medical ApS and therefore, monitors are not the subject of this 510(k) submission.

The OperaScope is supplied as a sterile, single use device and the Recording Module is supplied as a non-sterile reusable unit. The OperaScope contains a miniature Complimentary Medical Oxide Semi-conductor (CMOS) camera and a Light-Emitting Diode (LED) illumination at the tip, a channel for infusion of irrigating fluid and a channel for fluid outflow, a display unit (LCD display), microelectronics, firmware and single use batteries for powering the device. The Recording Module contains microelectronics, software, controls for recording pictures and video sequences, USB port for storage of pic/video, HDMI port for connection of the OperaScope, HDMI port for connecting an external monitor and an input port for external 9V DC power supply.

Model Numbers

Ref. number	Description
OP-201-1	**LiNA OperaScope™** with HDMI cable and on-board LCD – single unit
OP-201-6	**LiNA OperaScope™** with HDMI cable and on-board LCD – 6 units
OP-RM-1	LiNA OperaScope™ Recording Module

8. Substantial Equivalence Discussion

1) U-Scope 8000 HSC + EMB Cannula (K132384)

The OperaScope is substantially equivalent to the EndoSee Corporation's U-Scope 8000 HSC+EMB Cannula (K132384) in terms of technological characteristics and intended use.

2) Gyrus ACMI Invisio Digital Hysteroscope System (K092278)

The OperaScope is substantially equivalent to the Gyrus ACMI Invisio Digital Hysteroscope System (K092278) in terms of indication for use.

Table B compares the OperaScope to the predicate devices with respect to the mode of operation, technological characteristics, materials, and performance testing. The OperaScope is substantially equivalent to the U-Scope 8000 HSC+EMB Cannula (K132384) in terms of intended use and technological

characteristics such as the CMOS camera, LED illumination, inflow/outflow channel, image capturing features and LCD display unit and to the Gyrus ACMI Invisio Digital Hysteroscope System (K092278) in terms of indication for use.

Table B – Comparison of Characteristics

Manufacturer	**LiNA Medical ApS**	**EndoSee Corporation**	**Gyrus ACMI Inc.**
Trade Name	**OperaScope**	**U-Scope 8000 HSC+EMB Cannula**	**Gyrus ACMI Invisio Digital Hysteroscope System**
510(k) Number	K171113	K132384	K092278
Product Code	HIH	**SAME**	**SAME**
Regulation Number	884.1690	**SAME**	**SAME**
Regulation Name	Hysteroscope and Accessories	**SAME**	**SAME**
Intended Users	Trained Medical Professionals	**SAME**	**SAME**
Site of Use	Hospitals and Physician Offices	**SAME**	**SAME**
Device Features and Components	• Sterile/Single-Use Handpiece (Hysteroscope) with CMOS camera, LED illumination, LCD display unit, channel for infusion of irrigating fluid, channel for fluid outflow, microelectronics, firmware and single use batteries for powering the device. • Non-Sterile/Reusable Recording Module with software, microelectronics and controls for recording pictures/video sequences. USB port for storage of pictures/video, HDMI ports (2) for	• Sterile/Single-Use Biopsy Cannula with CMOS camera, LED illumination, channel for irrigating fluid, channel for aspiration of tissue. • Non-Sterile/Reusable HandTower with connector and locking mechanism to attach/detach cannula, LCD display unit, power button, illumination brightness adjuster, video processor, electronics, microcontrollers, firmware for capture of single image/video procedures, rechargeable battery.	• Non-Sterile (sterilization by the user)/Reusable Hysteroscope with CMOS sensor, LED light source, electrical wiring, printed circuit board (PCB), electrical cord to connect to the Camera Control Unit (CCU) • Non-Sterile/Reusable Camera Control Unit (CCU) with PCBs, software, power supply, power cables to process and display images transmitted by the camera.

Manufacturer	LiNA Medical ApS	EndoSee Corporation	Gyrus ACMI Inc.
Trade Name	**OperaScope**	**U-Scope 8000 HSC+EMB Cannula**	**Gyrus ACMI Invisio Digital Hysteroscope System**
	connection to handpiece (hysteroscope) and external monitor and input port for external 9V DC power supply.		
Optical Image	Digital CMOS Technology	**SAME**	**SAME**
Image Resolution	CMOS camera consists of approximately 160,000 pixels	**SAME**	Approximately 50,000 pixels
Illumination Light Source	LED at tip of cannula	**SAME**	LED integrated in handle
Light at 20mm from target. Range high to low level [LUX]	322 - 66 LUX	325 - 74 LUX	675 - 670 LUX
Inflow/outflow channel design	*Inflow:* Inflow channel and working channel combined in one channel above the camera. *Outflow:* One outflow channel with two entrances placed on top and bottom of distal tip.	*Inflow:* Inflow occurs through two smaller inflow channels on each side of the camera. *Outflow:* No outflow channel.	*Inflow:* Inflow channel and working channel combined in one channel below the camera. *Outflow:* No outflow channel.
Cannula tip design	Rounded polymer tip. Angled shaft proximal to tip (~20°). Steerable by rotation knob.	Rounded polymer tip. 25° angled shaft proximal to tip. Steerable by rotation of device.	Rounded stainless steep tip. Flexible. Sideward steerable 0 - 30° by control means on handle.
Image Transmission	Transmits images from CMOS video camera to local LCD display unit on the handpiece and remote monitor	Transmits images from CMOS video camera to local LCD display unit on the HandTower	Transmits images from CMOS video camera to remote monitor
Maximum Insertion Diameter (Tip)	4.3 mm	4.8 mm	5.5 mm with continuous flow sheath
Shaft/Cannula Length	240mm (24 cm)	270mm (27 cm)	Information not available

Manufacturer	LiNA Medical ApS	EndoSee Corporation	Gyrus ACMI Inc.
Trade Name	**OperaScope**	**U-Scope 8000 HSC+EMB Cannula**	**Gyrus ACMI Invisio Digital Hysteroscope System**
LCD Display Size	4.3 inches (diagonal)	3.5 inches (diagonal)	Not applicable
Energy Source	• Handpiece: 3V (2 AA batteries) • Recording Module: 9V DC external power adapter	3.7V Battery	CCU: 110-240V
Sterilization	• Handpiece (Hysteroscope): Ethylene Oxide (EO) • Handpiece Batteries: Radiation (gamma) • Recording Module: Non-Sterile	• Cannula: Ethylene Oxide (EO) • HandTower: Non-Sterile	• Hysteroscope: Non-Sterile • CCU: Non-Sterile
Tissue Contact Materials	Compliant with ISO 10993	**SAME**	**SAME**

The OperaScope shares the same or similar mode of operation, overall technical and functional capabilities as the predicate devices. In addition, the OperaScope is similar in design and function to the U-Scope 8000 HSC + EMB Cannula (K132384) in terms of mode of operation and use. The minor differences in the image transmission, cannula length and battery voltage do not raise any new issues of safety or effectiveness.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the OperaScope and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, LiNA completed a number of non-clinical performance tests. The OperaScope meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The OperaScope was subjected to safety and optical performance testing in accordance with the FDA's "Hysteroscopes and Gynecological Laparoscopes Submission Guidance for a 510(k)" (March 7, 1996).

The OperaScope passed all applicable testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Field of view and direction of view per ISO 8600-3
- Maximum width of insertion portion per ISO 8600-4
- Biocompatibility testing per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12
- EO and ECH residual testing per ISO 10993-7
- Electromagnetic Compatibility per EN/IEC 60601-1-2 (EMC and Immunity)
- Electrical Safety per AAMI/ANSI ES60601-1 and EN 60601-2-18
- Sterilization Validation per ISO 11135 (Ethylene Oxide – OperaScope), ISO 11137-1 and ISO 11137-2 (Radiation – OperaScope Batteries) and maintenance of sterilization per ISO 11737-2.
- Mechanical testing for bending (displacement), tensile strength and torque.
- Spatial Resolution utilizing ISO 3334 (test chart No. 2)
- Visualization and illumination study to determine the adequacy of imaging while in use in the uterine cavity utilizing a hysteroscopy simulator.
- In-flow and out-flow fluid delivery, including leak testing
- Fuctionality testing to verify compatibility of instruments and accessories with respect to dimensions
- Shelf-Life and Simulated shipping conditions per ASTM D4169
- Battery lifetime
- Software Validation and Verification per IEC 62304
- FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* [Moderate Level of Concern Applied to the OperaScope]
- FDA's guidance document *Hysteroscopes and Gynecologic Laparoscopes Submission Guidance for 510(K)*, including section V(E)(6b)/distortion characteristics.

10. Statement of Substantial Equivalence

The OperaScope, as designed and manufactured, is substantially equivalent to the predicate devices.