January 17, 2020

LiNA Medical ApS
% Kevin MacDonald
Regulatory Consultant
MacDonald Consulting
4297 D Street
Sacramento, CA 95819

Re: K193007
Trade/Device Name: LiNA OperaScope
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope And Accessories
Regulatory Class: Class II
Product Code: HIH, FAJ
Dated: November 13, 2019
Received: November 18, 2019

Dear Kevin Macdonald:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Jason R. Roberts, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193007

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 LiNA 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, polypectomy, transection of intrauterine adhesions and septa.

The LiNA OperaScope can also be used to permit viewing of the adult female urinary bladder through minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

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
K193007

1. Submitter's Name and Address:

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2. Submission Correspondent

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Sacramento, CA 95819
Office Phone: (415) 609-9875

3. Date Prepared

January 17, 2020

4. Device Identification

Trade/Proprietary Name:	LiNA OperaScope
Common/Usual Name:	Hysteroscope/Cystoscope
Classification:	21 CFR 884.1690 Hysteroscope and Accessories
Product Code:	HIH, Hysteroscope and Accessories
	FAJ, Cystoscope and Accessories, Flexible/Rigid
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology
	Gastroenterology/Urology

5. Legally Marketed Predicate Devices

- K171113: LiNA OperaScope
- K190639: Endosee System

There are no design-related recalls for these legally marketed predicate devices.

6. Indications 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 LiNA 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, polypectomy, transection of intrauterine adhesions and septa.

The LiNA OperaScope can also be used to permit viewing of the adult female urinary bladder through minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

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 LiNA 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 LiNA OperaScope is supplied as a sterile, single use device and the Recording Module is supplied as a non- sterile reusable unit. The LiNA 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 LiNA OperaScope, HDMI port for connecting an external monitor and an input port for external 9V DC power supply.

Model Numbers

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

8. Predicate Comparison

The table below compares the LiNA OperaScope to the predicate devices with respect to the indications for use and technological characteristics:

Manufacturer	**LiNA Medical ApS**	**LiNA Medical ApS**	**CooperSurgical, Inc.**
Trade Name	**OperaScope (K193007)**	**OperaScope (K171113)**	**Endosee System (K190639)**
Common Name	Hysteroscope, Cystoscope	Hysteroscope	Hysteroscope,Cystoscope
Product Code	HIH, FAJ	HIH	HIH, FAJ
Regulation Number	884.1690 876.1500	884.1690	884.1690 876.1500
Regulation Name	Hysteroscope and Accessories Gastroenterology/Urology Device	Hysteroscope and Accessories	Hysteroscope and Accessories Gastroenterology/Urology Device
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 LiNA 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, polypectomy, transection of intrauterine adhesions and septa. The LiNA OperaScope can also be used to permit viewing of the adult female urinary bladder through minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.	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.	The Endosee® System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic procedures. Generally recognized indications for diagnostic hysteroscopy include: • Abnormal bleeding • Infertility and pregnancy wastage • Evaluation of abnormal hysterosalpingogram • Intrauterine foreign body • Amenorrhea • Pelvic pain The Endosee® System can also be used to permit viewing of the adult urinary bladder through a minimally invasive approach by utilizing natural orifices to access the diagnostic site.
Intended Users	Trained Medical Professionals – Gynecologists/Urologists	Gynecologists	Same as Subject Device
Site of Use	Hospitals and Physician Offices	Same as Subject Device	Same as Subject Device

Technology Overview	Handheld battery-operated sterile and disposable single-use hysteroscope and cystoscope, which can be used for both diagnostic and therapeutic gynecological procedures. Non-Sterile/Reusable Recording Module with software, USB port for storage of pictures and video, HDMI ports (2) for connection to handpiece (hysteroscope / cystoscope) and external monitor and input port for external 9V DC power supply.	Same as Subject Device	Handheld battery-operated hysteroscope consisting of a reusable handle and a sterile, disposable, diagnostic cannula.
Cannula Type	Rigid	Same as Subject Device	Flexible
Patient Contact Materials	Compliant with ISO 10993	Same as Subject Device	Same as Subject Device
Working Channel	Yes	Same as Subject Device	Same as Subject Device
Maximum Insertion Portion Width	4.3 mm	Same as Subject Device	4.5mm
Illumination Light Source	LED at tip of cannula	Same as Subject Device	Same as Subject Device
Field of View	100^{o}	Same as Subject Device	Same as Subject Device
Pre-bend tip	$20^{o}\pm5^{o}$	Same as Subject Device	$20^{o}\pm3^{o}$
Shelf Life	12 months	Same as Subject Device	6 months
Image Display	LCD on handheld device and connection to external monitor.	Same as Subject Device	LCD on handheld device

The LiNA OperaScope has the same or similar indications for use and technological characteristics as compared to the predicate devices. The are no different questions of safety and effectiveness.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the LiNA 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 LiNA 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 LiNA 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 LiNA 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. Clinical Performance Data

Not Applicable

11. Conclusion

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