September 2, 2022

LiNA Medical ApS
℅ Scott Blood
Director of Regulatory Services
MEDIcept, Inc.
200 Homer Avenue
Ashland, MA 01821

Re: K221085
Trade/Device Name: LiNA OperaScope™ Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK, HIH
Dated: July 29, 2022
Received: August 4, 2022

Dear Scott Blood:

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 and Part 809); 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.
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)*
K221085

Device Name
LiNA OperaScope™ Needle

Indications for Use *(Describe)*
LiNA OperaScope™ Needle is intended for hysteroscopic injection into the uterine wall as well as for cystoscopic injection in the urinary bladder wall.

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™ Needle
K221085

1. Submission Sponsor

LiNA Medical ApS
Formervangen 5
DK-2600 Glostrup, Denmark
Contact: Jarosław Mrówczyński
Title: Regulatory Affairs Manager
Email: jmr@lina-medical.com
Office number: +48 61 222 21 21

2. Submission Correspondent

Scott Blood
Director of Regulatory Services
MEDIcept Inc.
200 Homer Ave
Ashland, MA 01721
Email: SBlood@medicept.com
Office number: +1 978-729-5978

3. Date Prepared

September 1, 2022

4. Device Identification

Trade/Proprietary Name:	LiNA OperaScope™ Needle
Common/Usual Name:	Needle
Classification Name:	Endoscope and Accessories
Regulation Number:	876.1500
Primary Product Code:	FBK
Reference Product Code:	HIH
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology

5. Legally Marketed Predicate Device(s)

Through FDA database search following predicate device has been identified: Cook Injection Needles manufactured by Cook Urological, Inc (K022484). **No design-related recalls for these legally marketed predicate devices have been identified.**

6. Indication for Use Statement

LiNA OperaScope™ Needle is intended for hysteroscopic injection into the uterine wall as well as for cystoscopic injection in the urinary bladder wall.

7. Device Description

LiNA OperaScope™ Needle is delivered as a sterile, single-use device designed to be used specifically with the LiNA OperaScope for hysteroscopic and cystoscopic injections. The device consists of a handle, a shaft and an injection needle, which is pointed at the distal end and has a luer-lock connection at the proximal end. Devices are packed in Tyvek pouches, with 6 units packed in a box. Model numbers are presented in Table 1.

Table 1 - LiNA OperaScope™ Needle reference numbers

Reference number	Description
OP-NEE4-6	LiNA OperaScope™ Needle 4mm, minimum channel diameter: Ø2.0mm
OP-NEE8-6	LiNA OperaScope™ Needle 8mm, minimum channel diameter: Ø2.0mm

8. Substantial Equivalence Discussion

Cook Injection Needle (K022484)

The LiNA OperaScope Needle is similar to the Cook Injection Needle in terms of indications for use and technological characteristics (required inner channel diameter, needle length, tip shape and presence of Luer lock).

Table 2 compares the LiNA OperaScope Needle to the predicate device with respect to the indications for use, principles of operation, materials, dimensions and operational mode. The predicate specifies needles are only intended to be used with rigid endoscopes.

Table 2 – Comparison LiNA OperaScope Needle and predicate device

Manufacturer	**LiNA Medical ApS**	**Cook Urological**
Trade Name	**LiNA OperaScope™ Needle (K221085)**	**Cook Injection Needles (K022484)**
Common Name	Endoscopic Injection Needle, Gastroenterology-urology;	Endoscopic Injection Needle, Gastroenterology-urology
Primary Product Code	FBK	FBK
Regulation Number	876.1500	876.1500
Regulation Name	Endoscope and Accessories;	Endoscope and Accessories
Indications for Use	LiNA OperaScope™ Needle is intended for hysteroscopic injection into the uterine wall as well as for cystoscopic injection in the urinary bladder wall.	The Cook Injection Needles are used to deliver a variety of injectable materials into tissues during laparoscopic, hysteroscopic, cystoscopic, endoscopic transurethral procedures and open surgical procedures. The type of material to be injected will be dependent on the nature of the procedure. The needle is intended to be used with legally marketed drugs and devices.
Intended Users	Trained Medical Professionals – Gynecologists and Urologists	Trained Medical Professionals – Gynecologists and Urologists
Site of Use	Hospital and Physician Offices	Hospital and Physician Offices
Route of advancement	Advanced to the bladder via the urethra and to the uterus via the cervix through the working channel of the endoscope.	Advanced to the bladder via the urethra and to the uterus via the cervix through the working channel of the endoscope.
Required channel inner diameter	5 Fr	3.7 to 9 Fr
Needle length	4 or 8 mm	Unknown
Needle width	23G	16-25G
Working length	313 mm	150 - 650 mm
Tip shape	3-bevel tip	3-bevel tip
Sterilization method	EtO	EtO
Duration of use	≤ 24 hours	≤ 24 hours
Frequency of use	Single use	Single use
Components	Injection Needle with Luer lock fitting to the syringe and protection cap for the tip	Injection Needle with Luer lock fit to the syringe
Patient Contacting Materials	The LiNA OperaScope Needle is tested according to ISO 10993 to assure that patient contacting materials are biocompatible.	Compliant with ISO 10993

Manufacturer	LiNA Medical ApS	Cook Urological
Trade Name	**LiNA OperaScope™ Needle (K221085)**	**Cook Injection Needles (K022484)**
Packaging	Tyvek pouch for single device, 6 devices packed in box	Tyvek-Poly Pouch
Shelf Life	36 months	36 months

LiNA OperaScope™ Needle is designed specifically for LiNA OperaScope and adjusted to the technical requirements of this device.

The LiNA OperaScope Needle has the similar indications for use and technological characteristics as compared to the predicate device. The differences in indications for use do not constitute a new intended use. Additionally, there are no different questions of safety and effectiveness that arise from the differences in technology. The technological differences between LiNA OperaScope Needle and the predicate device can be evaluated through performance testing and do not alter the intended use of the LiNA OperaScope Needle.

9. Non-Clinical Performance Data

In an effort to demonstrate safety and effectiveness of the LiNA OperaScope Needle and to support 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 Needle met all the requirements for overall design, sterilization and biocompatibility results confirming that the design output meets the design inputs and specifications for the device.

Functional Testing:

Functional bench testing was performed to demonstrate the adequate functionality of the LiNA OperaScope Needle, as follows:

- Insertion in Tissue <5N
- Exposure and retraction force <15N
- Detachable limit buckle present
- 360° rotation in LiNA OperaScope
- Distention fluid clearance
- Blockage of OperaScope camera
- Inability to pass needle with protective cap through OperaScope working channel
- The insertion and extraction force to/from OperaScope working channel <10N
- Visual Inspection
- Device Geometric Dimensions
- Device weight
- Device Surface
- Device robustness
- Biological Risk Assessment
- Bioburden Evaluation
- Endotoxin/LAL Evaluation
- Distention fluid clearance

The studies confirm that it is possible to insert the device into tissue of the uterine cavity, female urethra, and uterine bladder and function as described in the intended use.

Biocompatibility:

Biocompatibility studies were performed in accordance with the 2020 FDA guidance document “Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evlauation and “testing” as follows:

- Cytotoxicity: ISO 10993-5:2009
- Irritation: ISO 10993-10:2010
- Sensitization: ISO 10993-10:2010
- Acute Systemic Toxicity: ISO 10993-11:2017
- Material-mediated pyrogen: USP <151>, ISO 10993-11:2017
- Hemocompatibility: ASTM F756-17

Shelf-Life:

The LiNA OperaScope Needle has a shelf life of 3 years when packaged in Tyvek pouches, in accordance with the results of accelerated aged stability studies. Results from testing demonstrated that the devices could maintain their specifications over the stated shelf-life duration.

10. Clinical Performance Data

Not applicable for LiNA OperaScope Needle.

11. Statement of Substantial Equivalence

The LiNA OperaScope™ Needle has the same intended use as the predicate device. The LiNA OperaScope™ Needle has different technological characteristics from the predicate device, but these differences do not raise different questions of safety and effectiveness. Performance testing, as described above, demonstrates that the LiNA OperaScope™ Needle is as safe and effective as the predicate. Therefore, the LiNA OperaScope™ Needle is substantially equivalent to the referenced predicate device.