JAN 3 1 2014

5 510(k) Summary

1. **Submission Sponsor**
LINA Medical ApS
Formervangen 5
2600 Glostrup
Denmark
Phone: +45 43 29 66 66
Fax: -45 43 29 66 99
Contact: Louisa Memborg, Regulatory Affairs Officer

2. **Submission Correspondent**
Christine E. Nichols RAC
Boston Biomedical Associates
386 West Main Street, Suite 7
Northborough, MA 01532

3. **Date Prepared**
July 10, 2013

4. **Device Identification**

Trade/Proprietary Name:	LiNA Gold Loop HC
Common/Usual Name:	Hand Controlled Loop
Classification Name:	coagulator-cutter, endoscopic, unipolar (and accessories)
Classification Regulation:	21 CFR 884.4160
Product Code:	KNF
Device Class:	Class II
Classification Panel:	Obstetrics and Gynecology Panel

5. **Predicate Devices to which S.E is claimed:**
LiNA Loop K070315

6. **Device Description**
The LiNA Gold Loop HC is a 5 mm single use laparoscopic instrument. It is available with three different loop dimensions; EL-160-H (160mm x 80mm), EL-200-H (200mm x 100mm) and EL-240-H (240mm x 120mm), with an uninsulated cutting area of 30mm. The device is single use ethylene oxide sterilized and is compatible with most standard electrosurgical generators that provide a monopolar outlet.

7. Intended Use

The intended use has not been changed and is identical to the intended use of the LiNA Loop.

The LiNA Gold Loop HC is a 5mm monopolar electrosurgical device intended for cutting and removal of soft tissue in gynaecological procedures involving endoscopic hysterectomy. It is used with standard electrosurgical generators.

8. Comparison of Technological Characteristics

This special 510(k) is a modification to the LiNA Loop previously cleared by the FDA with the 510(k) number (K070315). The modifications include: the addition of the hand activation switch on the handle of the device; and a material change to the shrink tubing and gold plating on the cutting wire. No changes were made to the intended use, indications for use, energy type, performance specifications, sterilization method or fundamental scientific technology.

9. Non-Clinical Performance Data

Testing shows that the modified device complies with the same testing requirements as the predicate device which includes compliance to ISO10993-1:2009, IEC60601-1:2006 and ISO11135-1:2007.

The LiNA Gold Loop HC passed all the testing in accordance with national and international standards.

The LiNA Gold Loop HC testing supports the claim of substantial equivalence.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device LiNA Loop. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

The differences between the LiNA Gold Loop HC and the LiNA Loop do not raise any new questions regarding its safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the LiNA Gold Loop HC is substantially equivalent to the relevant aspects of the predicate device LiNA Loop in terms of design, components, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. LiNA Gold Loop HC, as designed is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

LiNA Medical ApS
% Christine Nichols RAC
Regulatory Affairs Manager
Boston Biomedical Associates
386 West Main Street, Suite 7
Northborough, MA 01532

Re: K132135
Trade/Device Name: LiNA Gold Loop HC
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: KNF
Dated: January 13, 2014
Received: January 14, 2014

Dear Christine Nichols,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
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

4 Indications for Use Statement

510(k) Number (if known): K132135

Device Name: LiNA Gold Loop HC

Indications for Use:

The LiNA Gold Loop HC is a 5mm monopolar electrosurgical device intended for cutting and removal of soft tissue in gynecological procedures involving endoscopic hysterectomy. It is used with standard electrosurgical generators.

Prescription Use__X__	AND/OR	Over-The-Counter Use _
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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