K070315

OCT 3 0 2007

5. 510(k) Summary

[As required by 21 CFR 807.92]

Submitted by	LiNA Medical ApS Formervangen 5 2600 Glostrup Denmark Phone: +45 4329 6666 Fax: +45 4329 6699
Contact person	Jane Kudsk, QA Manager
Date Prepared	January 25, 2007
Device trade name	LiNA Loop
Common name	Monopolar Endoscopic Loop
Classification name	Coagulator-Cutter, Endoscopic, Unipolar (And accessories) 21 CFR 884.4160, Product code KNF Class II

Intended Use
The LiNA Loop 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.

Description of Device
The LiNA Loop is a 5 mm laparoscopic instrument. It is available with two different loop dimensions; 160mm x 80mm and 200mm x 100mm. The outer 15mm on each side of the loop are not insulated i.e. the monopolar cutting area length is totally 30mm. The device is sterile for single use and is compatible with all standard electrosurgical generators that have a monopolar outlet.

Substantial Equivalence
The LiNA Loop is substantial equivalent to the Omnitech Resectoscope Cutting Loop Electrode (K981464) and the Cook Ireland Sonnet Polypectomy Snare (K050294) with respect to technical and design features. The submitted devices pose the same type of questions about safety or effectiveness as the existing devices.

Test Data
Test data include electrical testing which deems the LiNA Loop to be safe under those conditions. No clinical tests have been performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 2007

LiNA Medical ApS
% Mr. Walt Brittle
Vice President
FDA Compliance Help Desk, Inc.
1289 N. Fordham Blvd., Suite A-128
CHAPEL HILL NC 27517

Re: K070315
Trade Name: LiNA Loop
Regulation Number: 21 CFR 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: KNF
Dated: October 20, 2007
Received: October 22, 2007

Dear Mr. Brittle:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K070315

Device Name: LiNA Loop

Indications for Use:

The LiNA Loop 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
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