DEC 19 2013

6. 510(k) Summary

1. Submission Sponsor

LiNA Medical ApS
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Contact: Louisa Memborg, Regulatory Affairs Officer

2. Submission Correspondent

Christine Nichols RAC
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3. Date Prepared

September 9, 2013

4. Device Identification

Trade/Proprietary Name:	LiNA PowerBlade Plus
Common/Usual Name:	Bipolar forceps
Classification Name:	Electrosurgical, Cutting and Coagulation device and accessories.
Class. Regulation:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5. Predicate Device

LiNA PowerBlade (K063025)

6. Device Description

The LiNA PowerBlade Plus is a 5 mm single use instrument available in one 330mm length version with a 10mm jaw opening. The LiNA PowerBlade Plus is a bipolar forceps device that grasps and coagulates utilizing electrical current. Transecting is done with a sharp blade. LiNA PowerBlade Plus includes a rotation wheel on the handle that rotates the grasper jaws at the tip to improve positioning and ergonomics during the surgical procedure. The device is single use ethylene oxide sterilized and is compatible with most standard electrosurgical generators that provide a bipolar outlet.

7. Intended Use

The LiNA PowerBlade Plus is intended for use in open and laparoscopic surgery where grasping, coagulating and transecting is indicated.

8. Comparison of Technological Characteristics

The LiNA PowerBlade Plus is substantially equivalent to the predicate device with respect to technological characteristics. The devices have similar materials and principal of use, dimensions, as well as the same energy type, performance specifications and fundamental scientific technology.

9. Non-Clinical Performance Data

Testing was performed to demonstrate that the LiNA PowerBlade Plus complies with the same testing requirements as the predicate device which includes compliance to IEC60601-1:2006, IEC60601-2-18, and IEC60601-2-2, as well as Biocompatibility and sterilization requirements as shown by compliance to ISO10993-1, ISO1135-1, and ISO10993-7.

In addition, comparative functionality testing was performed which demonstrated that the grasping, cutting and coagulation performance of the proposed device was comparable to the predicate device.

The LiNA PowerBlade Plus testing demonstrates that the proposed and predicate devices are substantially equivalent.

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. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

Performance testing and compliance with voluntary standards, demonstrate that the LiNA PowerBlade Plus is substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, sterilization, biocompatibility, performance characteristics, and intended use. The LiNA PowerBlade Plus, as designed and manufactured, is 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

LiNA Medical ApS
% Ms. Christine E. Nichols
Boston Biomedical Associates
386 West Main Street, Suite 7
Northborough, Massachusetts 01532

December 19, 2013

Re: K132837
Trade/Device Name: LiNA PowerBlade Plus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 20, 2013
Received: November 21, 2013

Dear Ms. 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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Indications for Use Statement

510(k) Number (if known): K132837

Device Name: LiNA PowerBlade Plus

Indications for Use:

The LiNA PowerBlade Plus is intended for use in open and laparoscopic surgery where grasping, coagulating and transecting is indicated.

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)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.12.19 13:14:27 -05'00' for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K132837