MAR 1 1 2011

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	Louisa Memborg, Regulatory Affairs Officer
Date Prepared	5/27/2010
Device trade name	LiNA Xcise Laparoscopic Morcellator
Common name	Soft Tissue Morcellator and Accessories
Classification name	Laparoscope, Gynecologic (and accessories)
Predicate device(s) name, number, date cleared	(1)Gynecare laparoscopic Morcellator [GYNECARE X-TRACT Tissue Morcellator] K993801, cleared on 02/07/2000 (2) S*E*M*M* SET FOR MOTO DRIVE WISAP #7689 SSM (MODIFICATION) K960640, cleared on 02/14/1997

Intended Use

The LiNA Xcise Laparoscopic Morcellator is intended for gynaecologic endoscopic use by trained professionals in hospital and surgical clinic environments.

Description of Device

The LiNA Xcise Laparoscopic Morcellator is a single use, fully disposable, device that is supplied sterile. It has a self contained motor-unit and battery power-supply in a pistol grip housing with a trigger to control blade rotation and an integrated adjustable trocar housing containing a rotating cylindrical tube 15mm in diameter sharpened on the distal end to a cutting blade. The trocar housing is manually retractable to expose the cutting blade. The device includes duckbill housing with valve to restrict gas leakage. The morcellator is to be used with standard tissue graspers that are extended through the cylindrical tube to grasp the tissue to be morcellated by pulling it through the rotating

blade in a coring action. The device is single packed in blister package with tyvek lid. The package includes an obturator.

Indications For Use
Indicated for cutting, coring and extracting tissue in operative laparoscopy, including gynaecologic procedures such as hysterectomy and myomectomy.

Technological Characteristics
The essential technological characteristics of the device are substantially the same as the predicate devices.

Performance Data
Testing has been carried out with respect to:

- Test of cutting tube
- Test of trocar and trocar function
- Test of gearing/toothed wheels lifetime
- Test of motor, torque, motor-lifetime and morcellation functionality
- Test of ergonomics and trigger function
- Test of battery lifetime and electronics
- Test of battery post gamma sterilization
- Test of environment: Heat, vibration and noise
- Test of pull strength cutting tube
- Test of torque
- Test of speed (RPM)
- Test of EMC per EN 60601-1-2: 2007 FCC 47 CFR part 18
- Test cut rate g/minute

Clinical Data
No clinical data was deemed necessary to support this premarket notification. However, published literature is provided to demonstrate the safe and effective use of morcellation devices used for tissue removal during hysterectomy.

Substantial Equivalence Conclusions
The LiNA Xcise Laparoscopic Morcellator device does not raise any new issues of safety, effectiveness, or performance of the product. Based on the 510(k) summaries and information presented herein we have concluded that the LiNA Xcise Laparoscopic Morcellator is substantially equivalent to the Predicate Device(s) under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

LiNA Medical ApS
c/o Mr. Walter L. Brittle, Jr.
Managing Partner
FDA Compliance Help Desk, Inc.
1289 N. Fordham Blvd., Suite A-128
CHAPEL HILL NC 27517

MAR 11 2011

Re: K101458
Trade Name: LiNA Xcise™ Laparoscopic Morcellator
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: February 25, 2011
Received: March 1, 2011

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. 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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological 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): K101458

Device Name: LiNA Xcise™ Laparoscopic Morcellator

Indications for Use:

Indicated for cutting, coring and extracting tissue in operative laparoscopy, including gynaecologic procedures such as hysterectomy and myomectomy.

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)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101458