K102274

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510 (k) Summary

(revised)

Submission Type: Traditional

Date Prepared [21 CFR 807.92(a)(1)]
Revised June 13, 2011

JUN 15 2011

Submitter's Information [21 CFR 807.92(a)(1)]

Sponsor / Manufacturer
Mini Lap Technologies Inc.
88 Ashford Avenue - Dobbs Ferry, NY 10522
FDA Establishment Registration: 3007123990

Regulatory Contact
Curtis Raymond
Orchid Design - 80 Shelton Technology Center
Shelton, CT 06484

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: RaviNeedle™ Aspiration Instrument
- Common/Usual Name: Aspiration Needle
- Classification Names: Disposable Aspiration & Injection Needle
  Product code: GAA
  Class I per 21CFR 878.4800

Predicate Device [21 CFR 807.92(a)(3)]
Ximed Prosure Injection/Aspiration Needle Probes/Devices
(Ximed Medical/Prosure, Inc. – San Jose, CA)
Product Code: GAA
Premarket Notification: K983200

Description of the Device [21 CFR 807.92(a)(4)]
The RaviNeedle Aspiration Instrument is stainless steel needle approximately 12 inches in overall length. The proximal end of the device is fitted with a luer adapter which is fitted to a standard syringe (not supplied with the device). Using the standard syringe, the device is used to aspirate small volumes of fluid during either open or laparoscopic procedures. The device has a chisel-point tip to allow for percutaneous application. To maintain the position of the needle tip during multiple aspirations, the distal end of the needle is equipped with expandable wire cage/balloon which secures the needle to small structures being aspirated (e.g., the gallbladder). Use of the security feature is optional on the part of the user.

Specifications:

Materials	Stainless steel shaft with polyurethane; handle portion is made of polyethylene and poly carbonate
Diameter	2.8mm
Overall length	Approx 12 inches
Sterilization	Sterile/single use-disposable, gamma radiation; SAL = 10^{-6}
Suction Connector	Luer fitting to connect to standard syringe

Intended Use [21 CFR 807.92(a)(5)]
Mini-Lap Technologies RaviNeedle™ Aspiration Needle is indicated for use in endoscopic and open surgical procedures where it is appropriate to aspirate fluids.

Technological Characteristics [21 CFR 807.92(a)(6)]
The device has similar handle, safety, and needle design as other Mini Lap instruments. The device operates under low pressure as supplied by the syringe fitted to the device. The device is composed of similar materials to other Mini Lap instruments. The device is sterile and a single-use/disposable; users are specifically cautioned against reuse. The device is intended for removal of fluids only; it is not intended for injection of drugs or irrigation fluids. The device is substantially equivalent to other suction devices that have received FDA marketing clearance.

Performance Data [21 CFR 807.92(b)(1)]
The device has been assessed using either bench top or in-vivo testing for:

- Mechanical Integrity
- Tissue Penetration Forces
- Laparoscopic Visualization
- Cage deployment/retraction Forces
- Removal from Tissue
- Flow Rate
- Leak Rate
- Pneumoperitoneum Loss
- Security in Tissue
- Damage to Tissue
- Damage to Device

Testing showed the device meets all design criteria as well as the requirements of surgical users.

Conclusion [21 CFR 807.92(b)(3)]
We believe the features of the subject device are equivalent to those of other predicate devices. In-vitro and in-vivo testing demonstrates that the device will perform as stated in the indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mini Lap Technologies Inc.
% Orchid Design
Mr. Curtis Raymond
80 Shelton Technology Center
Shelton, Connecticut 06484

JUN 15 2011

Re: K102274
Trade/Device Name: Mini Lap Technologies – RaviNeedle Aspiration Needle
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: GAA
Dated: June 9, 2011
Received: June 10, 2011

Dear Mr. Raymond:

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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K102274

Indications for Use

510(k) Number (if known): K102274

Device Name: Mini Lap Technologies – RaviNeedle Aspiration Needle

Mini-Lap Technologies RaviNeedle Aspiration Needle is indicated for use in endoscopic and open surgical procedures where it is appropriate to aspirate fluids and retain tissue during aspiration of fluids.

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)

Mark R Ogden for MKN
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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