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

Mini Lap Technologies, Inc.
% Orchid Design
Mr. Joseph Azary
80 Shelton Technology Center
Shelton, CT 06484

JUL 27 2015

Re: K101101
Trade/Device Name: Mini-Tong
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): June 12, 2010
Received (Date on orig SE ltr): June 16, 2010

Dear Mr. Azary,

This letter corrects our substantially equivalent letter of July 23, 2010.

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,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known): K101101

Device Name: MINI-TONG

Indications For Use:

The devices are used for temporary grasping and clamping of soft tissue and small tubular structures during minimally invasive procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101101

k101101

Mini Lap Technologies Inc.

JUL 23 2010

510 (k) Summary

Submission Type:

Traditional 510(k)

Date Prepared [21 CFR 807.92(a)(1)]
[Revised July 12, 2010]

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

Regulatory Contact
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FDA Establishment Registration is 3007123990

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

Trade Name

- MINI-TONG Instruments

Device Common, Usual, or Classification Names

- Laparoscopic Instruments, Retractors, Cannula, Trocar, Manual Surgical Instruments

Classification Panel

- Classification of this device would fall under the responsibility of the Gastroenterology / Urology panel.

Class

Based on our research we believe the device is a class 2 device classified under the following Product Codes:

- KOG, 21 CFR 876.1500, Endoscope Accessories
- KOA, 21 CFR 876.4730 Manual Surgical Instruments
- FBQ, 21 CFR 878.5090 Trocar

Predicate Device [21 CFR 807.92(a)(3)]

- Mini Lap Instruments – K070686
- U.S. Surgical – Modified Hand Instrument Devices – K960748
- Solos Endoscopy – 10mm Atraumatic Grasping Forcep and 5mm Grasping Forcep – K900948 / K900958

Description of the Device [21 CFR 807.92(a)(4)]

The MINI-TONG instruments are minimally invasive devices. Prior to insertion, the physician must depress the safety button and retract the instrument into the needle. The needle is inserted through the soft tissue under visualization. Once the needle has penetrated the soft tissue, the physician will advance the instrument into the body cavity using the handle. As the instrument advances, the jaws of the instrument will open. The device includes a self-activating safety that prohibits the jaws from returning to their fully retracted position while in use.

The devices are sterile disposable, single patient only. The devices were designed to hold pneumoperitoneum during use.

Intended Use [21 CFR 807.92(a)(5)]

The devices are used for temporary grasping and clamping of soft tissue and small tubular structures during minimally invasive procedures.

Technological Characteristics [21 CFR 807.92(a)(6)]

We believe the MINI-TONG instruments are substantially equivalent to the predicate devices. The devices have the same technological characteristics as the predicate devices including identical handle design and safety interlock as well as are composed of biocompatible stainless steel.

Performance Data [21 CFR 807.92(b)(1)]

We believe the addition of this new jaw configuration is a minor expansion to a product family that already has 510(k) clearance. The subject device is composed of biocompatible materials and the sterilization process has been validated.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.