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FEB 12 2014

5.0 510(k) Summary

Applicant:	Steve Smith, CEO Liger Medical, LLC 825 N 300 West #NE127 Salt Lake City, UT 84103
Phone:	801-532-0221
Contact Person:	Jeremy Freed
Contact Phone:	801-243-6032
Date Prepared:	02/06/2014
Trade Name:	ESU-110
Common Name:	Electrosurgical and Suction Unit
Classification:	Electrosurgical cutting device and accessories (21 CFR 878.4400, Product Code GEI); and Gynecologic electrocautery and accessories (21 CFR 884.4120, Product Code HGI)
Predicate Device(s):	Finesse 3rd Generation (K123310) – Utah Medical Products, Inc; and Aaron 950 (K021817) – Bovie Medical Corporation
Device Description:	The Liger Medical ESU-110 combines a high-quality, class I type BF electrosurgical generator and a smoke evacuation system into a single, compact unit. This integrated system is designed to perform low-power excision procedures of short duration. The ESU-110 is designed to be portable, single-purpose, and is intended for non-hospital locations where A/C power may be unreliable or unavailable.

Dimensions

Height:	10.4" (26.4cm)
Width:	3.63" (9.29cm)
Depth:	12.0" (30.5cm)
Weight:	5.2 lbs (2.36kg)

Principle Materials: ABS plastic housing (UL-94HB rated), aluminum, ROHS-compliant electronic components

Indications for Use: The Liger Medical ESU-0110 is intended to deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting and/or coagulation of tissue. One intended use of the Liger Medical ESU-110 Electrosurgical Unit is Loop Electrosurgical Excision Procedure (LEEP).

Comparison to Predicate: The electronic circuitry in the Liger Medical ESU-110 operates in the same way as that of other electrosurgical generators; however, the circuitry is greatly simplified as a result of the device's limitation to a single purpose. These simplifcations can be delineated as follows:

- The output voltage and current waveform are not adjustable
- No power-level readout is necessary

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- Operator controls are limited to on/off and activation
- The circuitry is completely dead except for on/off and battery status indicator lights when the unit it not activated for patient application
- Output power is limited to under 50 watts, obviating the requirement for neutral electrode cable fault or pad adhesion alarms

The Liger Medical ESU-110 is powered by an internal lithium-ion battery to allow safe usage at locations where A/C line current is unavailable or unreliable. Battery operation also results in ready portability and more complete isolation than is achievable by a system powered by A/C line current.

The Liger Medical ESU-110 has an integrated smoke evacuation fan designed to remove smoke and noxious odors produced by surgical smoke during laser and electrosurgical procedures. This component of the system has been designed with a motor to draw the surgical smoke from the surgical site through vacuum tubing and into a microbial and charcoal filter where the surgical smoke is processed to remove odors. The smoke evacuation is completely automated with the activation being integrated into the activation circuit of the electrosurgical generator. When the Liger Medical ESU-110 is activated, the smoke evacuation fan automatically activates as well. This component of the Liger Medical ESU-110 is fouind to be substantially equivalent to the Utah Medical Products Finesse 3rd Generation. The smoke evacuation component of the Liger Medical ESU-110 presents virtually no potential for risk as there is only a single moving part which is fully encased and not accessible by the user. Further, the smoke evacuation component is never intended nor designed to come into contact with the patient and has no potential for electrical ground or shock.

The Liger Medical ESU-110 is substantially equivalent to the predicate devices Finesse 3rd Generation and Aaron 950 when taking into account that the ESU-110 is designed ot be a single-purpose, portable unit while the Finesse 3rd Generation and Aaron 950 are multi-purpose units. In terms of output type, number of connections, types of connections, activation method, indicators, safety class, patient circuit, output impedance, applied part classification, neutral electrode isolation, activation tone, leakage current, output mode, frequency, crest factor, activation cycle, ooutput controls, compatible accessories, compatible neutral electrodes, and audio frequency all three units are equivalent. The Liger Medical ESU-110 is equivalent to the predicate devices in terms of peak-to-peak voltage when the predicate devices are set to the fixed value of 49W which the Liger ESU-110 is designed to output. For each other parameter, the Liger ESU-110 is either exempt from regulation due to being limited to under 50W of output or is reflecting the properties of battery-operation vs. main line operation. Substantively, the Liger Medical ESU-110 is equivalent to the predicate devices.

Safety and Performance: The Liger Medical ESU-110 conforms to IEC 60601-1-2:2007 and IEC 60601-2-2:2009 requirements for electrical and electromagnetic safety passing the standard's requirements for patient protection, protection against neuromuscular stimulation, excessive temperatures, spillage, output indication, and protection against short circuits. Each of these safety concerns were tested in-house by Liger Medical and found to meet

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or exceed all applicable requirements of the IEC 60601-1-2:2007 and IEC 60601-2-2:2009. The outside intereference was negligible. Further, the ESU-110 generates no significant EMDs when idle, when activated, or when activated with a load. Compliance for both IEC 60601-1-1:2009 and IEC 60601-2-2:2009 are claimed in section 9.0. Specific testing protocols, testing procedures, tests conducted, and resulting data which support this summary are located in section 17.0.

In conclusion, the in-house test data collected for the Liger Medical ESU-110 strongly suggests that the ESU-110 unit is substantially equivalent to both the Bovie Aaron 950 and the Utah Medical Finesse 3rd Generation in both safety and performance.

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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

February 12, 2014

Liger Medical, LLC
Mr. Steve Smith
Chief Executive Officer
825 North 300 West, Suite NE127
Salt Lake City, Utah 84103

Re: K133273
Trade/Device Name: Liger Medical ESU-110
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HGI
Dated: December 31, 2013
Received: January 23, 2014

Dear Mr. Smith:

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,

Felipe Aguel

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

Enclosure

4.0 Indications for Use

510(k) Number (if known):	K133273
Device Name:	Liger Medical ESU-110
Indications For Use:	The Liger Medical ESU-110 is intended to deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting and/or coagulation of tissue. One intended use of the Liger Medical ESU-110 Electrosurgical Unit is Loop Electrosurgical Excision Procedure (LEEP).

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 Center for Devices and Radiological Health (CDRH)

Long H. Chen -A for BSA

(Division Sign-off)
Division of Surgical devices
510(k) Number: K133273