510(k) Summary

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92 the following summary of information is provided:

Date: 30 June 2013

Submitter: LCCS Products Limited
Add: FLAT 1801A ,18/F., ON HONG COMMERCIAL BLDG, 145 HENNESSY ROAD, WANCHAI, HONGKONG

Primary Contact Person: Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Co., Ltd.
Tel: (+86) 20-6232 1333
Fax: (+86) 20-8633 0253
Email: mike.gu@osmundacn.com

Secondary Contact Person: Mrs. Elizabeth Ma
Vice President
LCCS Products Limited
Tel: +852-81368758
Fax: + 852-35430978
Email: lccsmed@126.com

SEP 06 2013

Device: Trade Name: Single Use Grounding Pad
Common/Usual Name: Grounding Pad
Classification Names: Electrode, Electrosurgical

Product Code: GEI, JOS

Predicate Device(s): K120476, K052878

Device Description: The single use grounding pad is a non-sterile dispersive electrode with a pre-attached cord. The purpose of the return electrode is to complete the electrosurgical circuit between the generator, the active electrode and the patient. The grounding pad is to be used on any patient where full skin contact and a suitable placement site can be obtained. Use of this device for unintended application could lead to an unsafe condition.

Intended Use: This device is applied to the patient during electrosurgical procedures to provide a path for the RF current to leave the patient and return to the generator.

Technology:	The technological characteristics of the proposed device are identical to the predicate device. Both devices are intended for single use.
Determination of Substantial Equivalence:	Performance testing was conducted to validate and verify that the proposed device met all design specifications and was substantially equivalence to the predicate device: IEC 60601-2-2 Edition 5.0 2009-02 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories; Results of performance testing indicate that the grounding pad meets applicable sections of the standards referenced and are safe and effective for their intended use.
Conclusion:	The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices. Grounding Pad can be claimed to be Substantially Equivalent (SE) to the predicate device, K120476 and K052878.

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

September 6, 2013

LCCS Products Limited
% Mrs. Elizabeth Ma, Vice President
FLAT 1801A, 18/F., ON HONG COMMERCIAL
BUILDING 145 HENNESY ROAD, WANCHAI, HONGKONG

Re: K132136
Trade/Device Name: Single Use Grounding Pad
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, JOS
Dated: July 9, 2013
Received: July 11, 2013

Dear Mrs. Ma:

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,

Peter D. Rumm -A

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132136

Device Name: Single Use Grounding Pad

Indications for Use:

The Single Use Grounding Pad is applied to the patient during electrosurgical procedures to provide a path for the RF current to leave the patient and return to the generator.

Prescription Use_X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use___ (Part 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)

Joshua C. Nipper -S