



Food and Drug Administration
10903 New Hampshire Avenue
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August 19, 2016

TOP-RANK Health Care Co., Ltd
% Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China

Re: K160366

Trade/Device Name: Electrosurgical Disposable Grounding Pads
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: ODR
Dated: August 10, 2016
Received: August 15, 2016

Dear Ms. Hong:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,


Christopher J. Ronk -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K160366

Device Name

Electrosurgical disposable grounding pads

Indications for Use (Describe)

Electrosurgical disposable grounding pads are to conduct electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _K160366_____

1. Date of Preparation: 01/30/2016

2. Sponsor Identification

TOP-RANK Health Care Co. Ltd.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Mr. Lee Fu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Electrosurgical disposable grounding pads

Common Name: Electrosurgical Patient Return Electrode

Regulatory Information

Classification Name: Electrosurgical Patient Return Electrode

Classification: II

Product Code: ODR

Regulation Number: 21 CFR part 878.4400

Review Panel: General & Plastic Surgery

Intended Use Statement:

Electrosurgical disposable grounding pads are to conduct electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator.

Device Description

Electrosurgical disposable grounding pads construct of a layer of conductive aluminum foil with a foam as the supportive base of the pad. The aluminum foil is coated with adhesive hydro-gel layer. There is another film placed above the adhesive hydro-gel layer, which is used to protect the gel during the transportation and storage and will be removed prior to use.

They are available in different combinations of configurations, types, intended populations and conductive area.

They are not provided in sterile conditions and not required to be sterilized by the end user prior to operation. However, they are for single use only.

5. Identification of Predicate Device(s)

K091672

SHUYOU ELECTRIC MEDICAL SCIENCE CO., LTD.

Disposable Grounding Pad Series

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ✓ IEC 60601-1: 2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- ✓ IEC 60601-2-2: 2009 Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical access;
- ✓ IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- ✓ ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

- ✓ ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics (Scalpel System)

Item	Proposed Device(s)	Predicate Device(s)
Code	ODR	ODR
Regulation #.	21 CFR 878.4400	21 CFR 878.4400
Intended Use	Electrosurgical disposable grounding pads are to conduct electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator.	The Disposable Grounding Pad series devices are to conduct electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator.
Configuration	Single and Split aluminum film	Single and Split aluminum film
	Adult and pediatric	Adult and pediatric
	Single Use	Single Use
Biocompatibility	Adhesive hydro-gel Aluminum foil POLYESTER (PET) Foam (Polyster Fibre) Tested with ISO 10993 Series Standards	Adhesive hydro-gel Aluminum foil PET Foam Tested with ISO 10993 Series Standards
Electrical Safety	IEC 60601-1:2005 IEC 60601-2-2: 2009	IEC 60601-1 IEC 60601-2-2
EMC	IEC 60601-1-2: 2007	IEC 60601-1-2

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.