



Food and Drug Administration  
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October 9, 2015

DRTV Asia Ltd.  
c/o Media Trade Corporation  
Attn: Guenter Ginsberg, President  
11820 Red Hibiscus Dr.  
Bonita Springs, FL 34135

Re: K151693  
Trade Name: Dr-Ho's Foot Pad Electrode  
Regulation Number: 21 CFR 882.1320  
Regulation Name: Cutaneous electrode  
Regulatory Class: Class II  
Product Code: GXY  
Dated: September 8, 2015  
Received: September 10, 2015

Dear Mr. Ginsberg:

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,

**Michael J. Hoffmann -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological and  
Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151693

Device Name

Dr-Ho's Foot Pad Electrode

Indications for Use (Describe)

The Cutaneous Electrodes, "Dr-Ho's Foot Pad Electrodes", are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The cutaneous electrodes will deliver the stimulation signals generated by the stimulator to the bottom of the feet which they are in contact with.

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.

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# **510(k) SUMMARY**

**Date of Summary Prepared:** 06/02/2015 (revised 10.7.15)

**1. Submitter's Name:** DRTV Asia, Ltd.

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## **2. Proposed New Device:**

Trade Name: Dr-Ho's Foot Pad Electrode

Classification Name: Cutaneous Electrode

Regulation Number: 882.1320

Product Code: GXY

Classification Panel: Neurology

Device Class: II

## **3. Predicate (cleared) Devices:**

Predicate 1: TENS BACK PAIN RELIEF SYSTEM, Model EM38  
(TENS Belt with sewn-in Electrode Patches)

510(k) Number: K113321

Manufacturer: Savia Limited, China

Predicate 2: OTC TENS FOR LOW BACK PAIN RELIEF, MODEL WL-2407  
(TENS Belt with sewn-in Electrode Patches)

510(k) Number: K063660

Manufacturer: Well-Life Healthcare Ltd., Taiwan

#### **4. Description of Proposed Device:**

The Dr-Ho's Foot Pad Electrode is a foot-shaped, flexible piece of conductive silicone rubber with a receptacle for a wire that connects the device with electrical stimulation devices such as transcutaneous electrical nerve stimulators (TENS) or powered muscle stimulators (PMS).

To stimulate the bottom of the foot the patient simply connects the Foot Pad to a TENS unit, places the Foot Pad onto the floor and then places the foot onto the Foot Pad for stimulation with the TENS device.

The Foot Pad Electrode has a female pin receptacle which accepts the lead wire from the stimulator. The entire Foot Pad Electrode is made up of conductive material to provide uniform current distribution when connected to a stimulator.

The devices can be used dry or wet when in contact with the skin. The entire surface (approx. 35 in<sup>2</sup>) of the Foot Pad Electrode is very conductive, having a resistance of less than 7 ohms per inch. This low resistance provides low current density with uniform current distribution.

The following tests were performed:

ISO 10993-10 Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization (Irritation Study **in** Rabbits)

ISO 10993-5 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity. ISO

10993-10 Biological evaluation of medical devices, Part 10: Test for irritation and skin sensitization. (Irritation Study **in** Guinea Pigs)

#### **5. Indication for Use:**

The Cutaneous Electrodes, "Dr-Ho's Foot Pad Electrodes", are intended to be used with legally marketed electrical stimulating devices such as transcutaneous electrical nerve stimulators or powered muscle stimulators. The cutaneous electrodes will deliver the stimulation signals generated by the stimulator to the bottom of the feet with which they are in contact. The Foot Pad Electrodes are made up of conductive silicone rubber.

#### **6. Environment of Use:**

Clinics, Hospitals and home environments

#### **7. Contraindications:**

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.

Do not use this device together with a body-worn medical electronic device such as an ECG.

### **8. Technological Characteristics Compared to the Predicate Device**

Both, the Dr-Ho's Foot Pad Electrode and the sewn-in Electrode Patches of the named predicate devices have the same intended use and fundamental technology. All units provide electrically generated pulses from a transcutaneous electrical nerve stimulator to the skin. Dr-Ho's Foot Pad Electrode can be viewed as substantially equivalent to the predicate devices' Electrode Patches.

The electrical stimulation provided by Dr-Ho's Foot Pad Electrodes is substantially equivalent to that of the predicates and is commonly employed by TENS devices that have been cleared for marketing without prescription labeling; i.e. for OTC sale. Technological characteristics, features, specifications, materials and intended uses of the subject device are substantially equivalent to the quoted predicate device. The differences that exist between the devices, mainly in shapes and sizes, are insignificant in terms of safety or effectiveness.

### **9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:**

DRTV Asia, Ltd did not conduct, nor rely upon, clinical tests to determine substantial equivalence of the *Dr-Ho's Foot Pad Electrodes* vs. the predicate.

ISO 10993-10 Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization (Irritation Study in Rabbits)

ISO 10993-5 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity. ISO

10993-10 Biological evaluation of medical devices, Part 10: Test for irritation and skin sensitization. (Irritation Study in Guinea Pigs)

#### **b. Biocompatibility**

The material of the subject electrodes has been tested for biocompatibility as per ISO Standards below:

ISO 10993-10 Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization (Irritation Study in Rabbits)

ISO 10993-5 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity.

ISO 10993-10 Biological evaluation of medical devices, Part 10: Test for irritation and skin sensitization. (Irritation Study in Guinea Pigs)

The skin contact duration is class A =  $\leq$  24 hrs.

**c. Software**

There is no software in this product.

**d. Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the Dr-Ho's Foot Pad Electrodes can be cleaned by the use of the methods described in the Instruction Manual.

Sterilization is **not** required.

**8. Conclusions:**

The Dr-Ho's Foot Pad Electrodes have the same intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted device could maintain the same safety and effectiveness as that of predicate device. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the Dr-Ho's Foot Pad Electrodes are substantially equivalent to the predicate device.

# Typical Application of the Foot Pat Electrodes

