EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

JUN 2 0 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 on February 10, 2011.

The assigned 510(k) number is: K110509 .

1. Submitter's Identifications:

   Establishment:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Registration Number: 9616877
   Operations: Manufacturer

   Owner/Operator:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address : 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Contact Person: Robert Tu
   Phone : 886-2-2662-0038
   Fax No: 886-2-2664-5566
   e-mail : tu922@ms35.hinet.net

2. Name of the Device:
   Everyway Interferential Stimulator, model IF-908.

3. Information of the 510(k) Cleared Device (Predicate Device):
   Theratech IF series True sine interferential stimulator, model WL-2206A(K050847).

4. Classification Information:
   Trade/Device Name: Everyway Interferential Stimulator, model IF-908.
   Regulation Number: Unclassified
   Regulation Name: Interferential Current Therapy
   Regulatory Class: II
   Product Code: LIH

5. Device Description:

   The Everyway IF-908 Interferential stimulator is the device which generates the small ture-sine pulses of electrical current. The generated current may be delivered to the patient skin and/or underlying nerves through the cable and electrode placed on skin. Through the current stimulation the chronic and/or acute pain is to be relieved

   The Everyway IF-809 interferential stimulator consists mainly of two parts: the stimulus generator, and electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief

The stimulation current is generated in such a way that the frequency in channel 1 is fixed, but frequency in channel 2 is adjustable. Also the output amplitude is also adjustable. Those adjustable parameters could provide user some stimulation output change depending upon the condition of patients according to the prescription of physician. In general IF-908 is the prescription device, which needs the physician instruction for stimulation treatment.

IF-908 provides two different alternative power supply system. <1> 9V internal battery, <2> 9V rechargeable battery pack charged by adaptor. The operator may recharge 9V battery pack for long term use via the power rechargeable battery system of IF-908. The battery pack can not be charged during operation via using 9V battery pack power.

6. Intended Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain. It is intended for use on the order of a physician only.

7. Comparison to the 510(k) Cleared Device (Predicate Device):

The Everyway Interferential Stimulator, model IF-908 is substantially equivalent to the Theratech IF series True sine interferential stimulator, model WL-2206A(K050847) without any significant difference in main technological and operational feature.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of IF-908 are as the followings:
   1> Performance Compliance Test according to ANSI/AAMI NS4 conducted by manufacturer
   2> Electrical Compliance Test according to IEC 60601-1 by accredited laboratory.
   3> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:
   No particular Clinical Test was conducted for Everyway Interferential Stimulator, model IF-908.

10. Conclusions
    The Everyway Interferential Stimulator, model IF-908, has the same intended use and technological characteristics as the cleared device of Theratech IF series True sine interferential stimulator, model WL-2206A(K050847). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

    In the other words, Everyway Interferential Stimulator, model IF-908 is substantial equivalent with the Theratech IF series True sine interferential stimulator, model WL-2206A(K050847).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 20 2011

Everyway Medical Instrument Co., Ltd.
Mr. Robert Tu
3 Fl., No. 5, Lane 155, Sec. 3
Peishen Road
Shenkeng Hsiang
Taipei Hsien 222
Taiwan

Re: K110509
Trade/Device Name: Everyway Interferential Stimulator, model IF-908
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LIH
Dated: May 17, 2011
Received: May 19, 2011

Dear Mr. Tu:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Keoia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

Indications For Use

510(k) Number (if known): K110509

Device Name: **Everyway Interferential Stimulator, model IF-908.**

Indications For Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain. It is intended for use on the order of a physician only

Prescription Use √ 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)

Daniel L. Kaufman

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110509