K092627

JAN 1 4 2010

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File No: WMI-04-CT2011-FDA-05
Version: 1.1

510(k) SUMMARY

CT2011 SonicStimu, K ( )

Submitter's Name: Shenzhen Dongdixin Technology Co., Ltd.

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Contact: Zhigang Zhao

Date Prepared: Aug, 8 2009

1. Proposed Device:

Trade Name: CT2011 SonicStimu Pain Relief Device
Classification Name: Ultrasound and Muscle Stimulator
21 CFR 890.5860
Class II
Product Code: IMG, GZJ

2. Predicate Device:

21 CFR 890.5860
Product Code: IMG, GZJ, LIH
Device Class: II
Legally Marketed Device: Sonicator Plus 940, ME940
Manufacturer: Mettler Electronics Corp
510(k) Number: K071137

3. Description of Proposed Device:

The CT2011 SonicStimu Pain Relief Device is comprised of following main components:

- A system console including software and control electronics;
- A control and display panel;
- Device accessories including AC-DC Adaptor, Electrode 40*90mm, Lead for adapter, Lead for electrical.

The CT2011 is a single channel combination unit for therapeutic ultrasonic and transcutaneous electrical nerve stimulation. The microprocessor in CT2011 provides pro-modulated low frequency and monophasic electrical pulse waveforms with enhanced reliability and ease of using of the device. In the same time it offers 1 MHz ultrasound treatment also.

The user interface friendly comprises keys, LCD and audio feedback. The LCD provides operator information about operation mode and signal intensities. The user through control buttons to make adjusting power for ultrasound and stimulation. The CT2011 can be used as electrical stimulation or ultrasound therapeutic equipment separately or combination for both.

4. Proposed Device Intended Use Statement:

Device Name: CT2011 SonicStimu Pain Relief Device

Proposed Device Indications for Use:

Therapeutic Ultrasound

1. Pain relief
2. Reduction of muscle spasm
3. Joint contractures

Transcutaneous Electrical Nerve Stimulation

1. Symptomatic relief of chronic intractable pain
2. Post-traumatic pain
3. Post-surgical pain

5. Biocompatibility Certification:

Electrodes to be provided with this device are from the manufacturer Top-Rank Health Care Equipment Co., Ltd (K070612) who submitted in 2007.

The shell of device is used ABS material; this material has passed Biocompatibility testing in Jiangsu TUV Product Service Ltd. Shanghai Branch. Identification No: 080960.

Ultrasound transducer attached to a metal surface and patient contact through the metal, this material is aluminum that passed biocompatibility testing in School of Radiation Medicine and Public Health Soochow University. The testing report No: SRPSU-2008-0544, SRPSU-2008-0545, SRPSU-2008-0546,

6. Technological Characteristics and Substantial Equivalence

Both the CT2011 SonicStimu Pain Relief Device and the Predicate device Stimulator have the same intended use and fundamental technology under the same product code. A side-by-side comparison of the CT2011 SonicStimu Pain Relief Device and the cited predicate devices is included in the 510(k) submission. The CT2011 SonicStimu Pain Relief Device is substantially equivalent to the technological features as the predicate devices.

Basic technological characteristics, new device vs. Predicate device

1	510K#	K	K071137
2	Device Name	CT2011	Sonicator Plus940
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	Mettler Electronics
4	Power Source	DC 15V /1A	AC Line
	-Method of Line current isolation	Reinforced insulation	Reinforced insulation
	- Patient Leakage Current (μA) -Normal condition -Single fault condition	 <1 >50	 >50 >50
5	Number of Output Modes	15	8
6	Number of Output Channels	1	4
	Synchronous Or Alternating	N/A	1&2 or 3&4
7	Constant Current or Constant Voltage	Constant Voltage	Constant Current
8	Software/Firmware/Microprocessor Control	Yes	Yes
9	Automatic Overload Trip	Yes	Yes
	Automatic Over Current Trip	Yes	Yes
10	Automatic No Load contact Trip	Yes	Yes
11	Automatic Shut off	No	Yes
12	Patient Override Control?	No	No
13	Indicator Display		
	-On/Off Status	Yes	Yes
	-Voltage/Current Level?	Yes	Yes
	-Low Battery indicator	N/A	N/A
14	Timer Display	0-30 minutes	0-60 minutes
15	Standards	ISO14971, UL60601-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, MDD 93/42/EEC, Annex II	ISO14971, UL2601-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, MDD 93/42/EEC, Annex II
16	Compliance with 21 CFR 898	Yes	Yes
17	Weight (lbs.)	0.84	11
18	Dimensions (in.) H x W x L	14.1x2.5x3.8	4.9x13.6x10.5
19	Housing Materials & Construction	Plastic	Metal Casing

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The CT2011 SonicStimu Pain Relief Device did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Nonclinical testing was performed in order to validate the design according with the company's specified design requirements, and to assure conformance with the following voluntary design standards:

- IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for safety".
- IEC 60601-1-2 "Medical electrical equipment - Part 1-2: General requirements for safety – Collateral Standard"
- IEC 60601-2-10 "Medical electrical equipment - Part 2: Particular requirements for the safety of nerve and muscle stimulators"
- IEC 60601-2-5 "Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment ED "

8. Discussion of Clinical Tests Performed:

Not applicable

9. *Conclusions:*

The CT2011 SonicStimu Pain Relief Device has the same intended use and similar characteristics as the predicate device, the Sonicator Plus 940, Model ME940 device. Moreover, bench testing, safety report and Risk Analysis Report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, The CT2011 SonicStimu Pain Relief Device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 1 4 2010

Shenzhen Dongdixin Technology Co., Ltd
% Mr. Zhigang Zhao
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Xilixiaobaimang Nanshan District
Shenzhen, CN-44, Guangdong Province
People's Republic of China 518108

Re: K092627
Trade/Device Name: CT2011 SonicStimu Pain Relief Device
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator.
Regulatory Class: Class II
Product Code: IMG, GZJ
Dated: January 8, 2010
Received: January 8, 2010

Dear Mr. Zhao:

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.

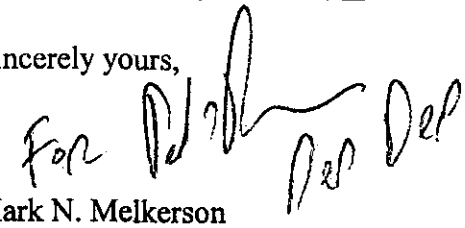
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/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,



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

Enclosure

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Indications for Use Statement

510(k) Number ( ):

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3. Post-surgical pain

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092627