K100117

Caretalk®

JAN 29 2010

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510(k) SUMMARY

LT3000 Series Electro-Stimulator, K ( )

Date of Submission: 12/10/2009

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

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Contact: Zhigang Zhao

1. Proposed Device:

A.

Trade Name:	LT3000 Combo Stimulator LT3002 EMS Stimulator
Classification Name:	Stimulator, Muscle, Powered
Regulation Number:	890.5850
Product Code:	IPF
Device Class:	II

B.

Trade Name:	LT3001 TENS Stimulator
Classification Name:	Stimulator, Nerve, Transcutaneous. For pain relief
Regulation Number:	882.5890
Product Code:	GZJ
Device Class:	II

2. Predicate Device:

Legally Marketed Device:	TENS/EMS Combo, TENS, EMS
510(k) Number:	K082514
Manufacturer:	MEDIHIGHTEC MEDICAL CO., LTD

3. Description of Proposed Device:

The LT3000 Series Stimulator, which includes models LT3000, LT3001 and LT3002, are Transcutaneous Electrical Nerve Stimulator and muscle stimulator for pain relief and/or Electrical Muscle Stimulator. The stimulator sends gentle electrical current to underlying nerves and muscle group through the cable and electrode placed on the skin. The parameters of units are controlled by the rotate buttons. Its intensity level is adjustable according to the needs of patients.

The three models LT3000, LT3001 and LT3002 have the same housing in a molded portable plastic case, an accessible buttons、switch, and accessible battery storage compartment. The case shape is rectangular. The process to set the parameter and attach lead wires to the three models is also the same except the Housing printing artwork, Mode No & destination.

The LT3000 Combo Stimulator is the combination unit with both TENS and EMS functions, the function can be selected by switch. The range of settings is identical to those of LT3001 and LT3002. The difference on the three units can be identified by

printing artwork, Mode No.

4. Proposed Device Intended Use Statement:

Device Name:

LT3000 Combo TENS/EMS Stimulator, LT3001 TENS Stimulator, LT3002 EMS Stimulator

Indications for Use:

LT3000 Combo Stimulator

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain
2. Increase of blood flow in the treatment area
3. Relaxation of muscle spasm
4. Immediate post-surgical stimulation of muscles to prevent venous thrombosis
5. Prevention or retardation of disuse atrophy
6. Muscle re-education
7. Maintaining or increasing range of motion.

LT3001 TENS Stimulator

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain

LT3002 EMS Stimulator

1. Relaxation of muscle spasm.
2. Increase of blood flow in the treatment area
3. Immediate post-surgical stimulation of muscles to prevent venous thrombosis
4. Muscle re-education
5. Prevention or retardation of disuse atrophy
6. Maintaining or increasing range of motion.

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.

6. Technological Characteristics and Substantial Equivalence

Both the LT3000 Series Electro-Stimulator and the Predicate device Stimulator have the same intended use and fundamental technology. A side-by-side comparison of the LT3000 Series Electro-Stimulator and the cited predicate devices is included in the 510(k) submission. The LT3000 Series Electro-Stimulator is substantially equivalent to the technological features as the predicate devices.

Basic technological characteristics, new device vs. Predicate device

		New device	Predicate device
1	510K#	K	K082514
2	Device Name	LT3000 Combo Stimulator LT3001 TENS Stimulator LT3002 EMS Stimulator	MH8000/MH6000 TENS/EMS Combo MH8100/MH6100 EMS MH8200/MH6200 TENS
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	Medihightec medical Co., Ltd
4	Power Source	9V Battery	9V Battery
	-Method of Line current isolation	Battery Supply N/A	Battery Supply N/A
	- Patient Leakage Current -Normal condition -Single fault condition	 1.1uA 1.3uA	 1.5uA 1.7uA
5	Number of Output Modes	6	7
6	Number of Output Channels	2 Synchronous and Alternating	2 Synchronous and Alternating
	Method of channel isolation	By enclosure	By transformer
7	Regulated Current or regulated Voltage?	Voltage control	Voltage control
8	Software/Firmware/ Microprocessor Control?	Yes	Yes
9	Automatic Overload Trip? Automatic Over Current Trip?	No No	No No
10	Automatic No Load Trip?	No	No
11	Automatic Shut off?	No	No
12	Patient Override Control?	No	No
13	Indicator Display		
	-On/Off Status?	Yes	Yes
	-Voltage/Current Level?	Yes	Yes
	-Low Battery?	Yes	Yes
14	Timer Range (minutes)	30min, 60min, continue	5~90minutes or continue
15	Waveform	Biphasic Rectangular	Biphasic Rectangular

16	Pulse Width Range	50-300us	50-300us
17	Frequency	2-120Hz	2-150Hz
18	Compliance with Voluntary Standards?	IEC60601-1, IEC60601-1-2,	IEC60601-1, IEC60601-1-2,
19	Compliance with 21 CFR 898?	Yes	Yes
20	Weight (grams.)	128 grams(battery included)	162grams(battery included)
21	Dimensions (cm.) L x W x H	10.2x6.4x2.6	13.6x7x2.7
22	Housing Materials & Construction	Enclosure: ABS,94, V-1,80℃,UL Approved	Enclosure: ABS,94, V-1,80℃,UL Approved

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

The LT3000 Series Electro-Stimulator 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"

8. **Conclusions:**

The LT3000 Series Stimulator, which includes models LT3000, LT3001 and LT3002, has the same intended use and technological characteristics as the predicate device. Moreover, bench testing, safety report and Risk Analysis Report documentation supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, the LT3000 Series Electro-Stimulator 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

Shenzhen Dongdixin Technology Co., LTD.
% Underwriters Laboratories, Inc.
Mr. Marc M. Mouser
2600 North West Lake Road
Camas, Washington 98607

JAN 29 2010

Re: K100117
Trade/Device Name: LT3000 Combo Stimulator, LT3001 TENS Stimulator, LT3002 EMS Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, GZJ
Dated: January 7, 2010
Received: January 15, 2010

Dear Mr. Mouser:

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

Caretalk®

File No: WMI-04-LT3000-FDA-04
Version: 1.0

Indications for Use

510(k) Number ( ):

Device Name:

LT3000 Combo Stimulator, LT3001 TENS Stimulator, LT3002 EMS Stimulator

Indications for Use:

LT3000 Combo Stimulator

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain
2. Increase of blood flow in the treatment area
3. Relaxation of muscle spasm
4. Immediate post-surgical stimulation of muscles to prevent venous thrombosis
5. Prevention or retardation of disuse atrophy
6. Muscle re-education
7. Maintaining or increasing range of motion.

LT3001 TENS Stimulator

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain

LT3002 EMS Stimulator

1. Relaxation of muscle spasm.
2. Increase of blood flow in the treatment area
3. Immediate post-surgical stimulation of muscles to prevent venous thrombosis
4. Muscle re-education
5. Prevention or retardation of disuse atrophy
6. Maintaining or increasing range of motion.

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 K100117