510(k):

KOALATY PRODUCTS, INC.
A Current Solutions Company

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

AUG 3 1 2010

# 510(k) SUMMARY

## TENS Electro-Stimulator, K ( 102014 )

**Date of Submission:** 4/15/2010

**510(k) Submitter's Name:** Koalaty Products.,INC

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## 1. Proposed Device:

| | |
|---|---|
| Trade Name: | TENS 2800 Stimulator TENS 3000 Stimulator |
| Classification Name: | Stimulator, Nerve, Transcutaneous. For pain relief |
| Regulation Number: | 882.5890 |
| Product Code: | GZJ |
| Device Class: | II |

## 2. Predicate Device:

| | |
|---|---|
| Predicate Device: | LT3001 TENS Stimulator |
| 510(k) Number: | K100117 |
| Manufacturer: | Shenzhen Dongdixin Technology Co., Ltd. |

## 3. Description of Proposed Device:

TENS Series Electro-Stimulator, which includes models TENS 2800 and TENS 3000, are Transcutaneous Electrical Nerve Stimulator for pain relief. The stimulator sends gentle electrical current to underlying nerves 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.

These TENS electro-stimulator have the same housing in a molded portable plastic case, an accessible、switch, and accessible battery storage compartment. The case shape is rectangular. The process to set the parameter and attach lead wires to the two models is also the same except the Housing printing artwork, Mode No.

TENS 3000 stimulator has three treatment mode: normal mode, burst mode and modulation mode. The treatment mode can by selected by switch. TENS 2800 only one treatment mode: normal mode. The difference on the two device can be identified by panel, Mode No.

## 4. Proposed Device Intended Use Statement:

Device Name:

TENS 2800 Stimulator, TENS 3000 Stimulator

**Indications for Use:**

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.

## 6. Technological Characteristics and Substantial Equivalence

Both the TENS Series Electro-Stimulator and the Predicate device Stimulator have the same intended use and fundamental technology. A side-by-side comparison of the TENS Series Electro-Stimulator and the cited predicate devices is included in the 510(k) submission. The TENS 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 | K100117 |
| 2 | Device Name | TENS 2800 Stimulator<br>TENS 3000 Stimulator | LT3001 TENS Stimulator |
| 3 | Manufacturer | Koalaty Products.,INC | Shenzhen Dongdixin Technology 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<br>-Normal condition<br>-Single fault condition | <br>1.2uA<br>1.3uA | <br>1.1uA<br>1.3uA |
| 5 | Number of Output Modes | 3 | 6 |
| 6 | Number of Output Channels | 2 | 2 |
| | Method of channel isolation | By enclosure | By enclosure |
| 7 | Regulated Current or regulated Voltage? | Voltage control | Voltage control |
| 8 | Software/Firmware/ Microprocessor Control? | Yes | Yes |
| 9 | Automatic Overload Trip?<br>Automatic Over Current Trip? | No<br>No | No<br>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) | 15min, 30min, continue | 30min, 60min, continue |
| 15 | Waveform | Biphasic or Monophasic Rectangular pulse | Biphasic Rectangular pulse |
| 16 | Pulse Width Range | 30-260us | 50-300us |
| 17 | Frequency | 2-150Hz | 2-120Hz |
| 18 | Compliance with Voluntary Standards | IEC60601-1, IEC60601-1-2, IEC60601-2-10 | IEC60601-1, IEC60601-1-2, IEC60601-2-10 |
| 19 | Compliance with 21 CFR 898? | Yes | Yes |
| 20 | Weight (grams.) | 115 grams(battery included) | 128 grams(battery included) |
| 21 | Dimensions (mm.) H x W x T | 95x65x23.5 | 102x64x26 |
| 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:

TENS 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 TENS Series Stimulator, which includes models TENS 2800 and TENS 3000, 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 TENS 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 –WO66-G609
Silver Spring, MD 20993-0002

Koalaty Products, Inc.
c/o Mr. Jeffrey D. Rongero
Senior Project Engineer, UL Health Sciences
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle, NC 27709

AUG 31 2010

Re: K102014
Trade/Device Name: TENS 2800, TENS 3000
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: GZJ
Dated: August 11, 2010
Received: August 16, 2010

Dear Mr. Rongero:

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/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,

Kesia Alexander

for 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

K102014

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# Indications for Use

AUG 31 2010

510(k) Number ( K102014 ):

Device Name:

TENS 2800 Stimulator TENS 3000 Stimulator

## Indications for Use:

Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K102014