K070299

JUL 16 2007

510(K) SUMMARY

Prepared Date: June 21,2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. **Submitter's Name:** **ezFit Technology, Inc.**

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Contact: Mr. OU YANG / Vice President

2. **Device Name :**

Trade Name: **ezFit Digital Heating TENS (Model No.: HR-661/UC-101)**

Common Name: TENS unit

Classification name Transcutaneous Electrical Nerve Stimulator (21CFR 882.5890)
Powered heating pads (21 CFR 890.5740)

3. **DEVICE CLASS** ezFit Digital Heating TENS (Model No.: HR-661) have been classified as

- Transcutaneous Electrical Nerve Stimulation Device,
  Regulatory Class: II
  Product Code: GZJ
  Regulation Number: 21CFR 882.5890
- Powered heating pad,
  Regulatory Class: II
  Product Code: IRT
  Regulation Number: 21CFR 890.5740

4. **Predicate Device:** The predicate device is the

- **ELFcare (K023231) ,** model no. : 314A, 314B, 314C , marketed by **Mediseb Ltd.**
- **SHIAN JIA MEEI TWO Channel Digital T.E.N.S (K052182)** marketed by **SHIAN JIA MEEI ENTERPRISE CO., LTD.**

5. **Device Description:** **ezFit Digital Heating TENS(Model No.: HR-661/ UC-101)** (Transcuntaneus Electrical Nerve Stimulator) is designed for symptomatic relief and management of chronic intractable pain.

ezFit Digital Heating TENS(Model No.: HR-661/ UC-101) is of independent two channels output (double output), the user can choose

to use a single channel connecting to two electrode pads or using both channels with four electrode pads simultaneously. With large LCD panel. It is powered by 3.6V(1.2V x 3)Ni-H Rechargeable Batteries or AC-DC adaptor.

The **ezFit Digital Heating TENS(Model No.: HR-661/ UC-101)** is a TENS (Transcuntaneus Electrical Nerve Stimulator) that employs a combination application of previously well known electrical and temperature treatment modalities for pain relief and rehabilitation. The system is based on a combination of thermal transfer (Powered heating pads - 21 CFR 890.5740) and conventional TENS - 21 CFR 882.5890) therapy.

When used in either Compress heat function only or Compress heat function plus TENS , An electronically controlled thermoelectric electrode pads can provide automatic thermal control with a Range of 36℃- 42℃. The Dual output can be adjusted to provides thermal heat to the skin between 40 and 42 °C for at least 10 minutes as therapeutic heating. This automatic thermal control mechanism also avoid skin from thermal injury.

Model No. description

HR-661/UC-101 is all the same except the Housing printing artwork , model no. & destination.

6. Intended Use:

For Transcutaneous Electrical Nerve Stimulation, ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for

- symptomatic relief and management of chronic intractable pain.

For Powered heating therapy , ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for

- Temporary relief of minor aches and pains and muscle spasms

7. Performance Summary:

The device conforms to applicable standards includes ISO 14971, IEC 60601-1, IEC 60601-1-2 and related standard.

Software Validation Study , Waveform & output Study & Skin temperature study are performed to demonstrate the safety and effectiveness of the device.

8. Conclusions:

The ezFit Digital Heating TENS(Model No.: HR-661/ UC-101) has the same intended use and similar technological characteristics as the ELFcare (K023231) , model no. : 314A, 314B, 314C , marketed by Mediseb Ltd. & SHIAN JIA MEEI TWO Channel Digital T.E.N.S (K052182) marketed by SHIAN JIA MEEI ENTERPRISE CO., LTD. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the ezFit Digital Heating TENS(Model No.: HR-661/ UC-101) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EzFit Technology, Inc.
C/O Thomas Huang
Project Engineer
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, Washington 98607

JUL 16 2007

Re: K070299
Trade/Device Name: ezFit Digital Heating TENS (Model #: HR-661/UC-101)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator (TENS)
Regulatory Class: Class II
Dated: June 28, 2007
Received: July 2, 2007

Dear Mr. Huang:

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.

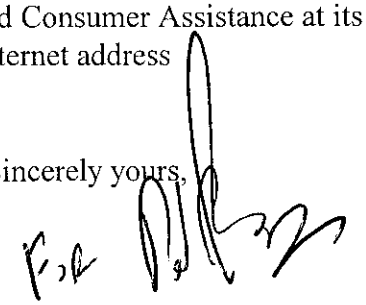
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



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

Enclosure

Indications for Use

510(k) Number (if known): *K070299*

Device Name: **ezFit Digital Heating TENS (Model No.: HR-661/ UC-101)**
ezFit Technology, Inc.

Indications For Use:

For Transcutaneous Electrical Nerve Stimulation, ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for

- Symptomatic relief and management of chronic intractable pain.

For powered heating therapy, ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for

- Temporary relief of minor aches and pains and muscle spasms

Prescription Use V AND/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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070299