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K040253
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510(k) Summary

Submitter: EasyMed Instrument Co., Ltd
Add: 2/F-3/F. No.2 BeiHai Da Rd LunJiao, Shunde, Guangdong, China
Tel: 0086-765-7727282 7727283 Fax: 0086-765-7727868

Submitted Device:

Trade name: EasyMed TN-28C TENS UNIT
Common name: Transcutaneous Electrical Nerve Stimulator (T.E.N.S)

Identification of the legally marketed device

The legally marketed device which EasyMed is claiming equivalence:
510(k) No: K994266
Device name: FDTENS 2010
Manufacturer: Fuji Dynamics Ltd

The TN-28C TENS Unit is SE to the FDTENS 2010, their circuits design are based on the same principle; Both of them use two 1.5V AA batteries and have two output channels; their output electrical parameters, frequency, pulse width, and intensity, etc., are very similar substantially

Description of the submitted device

T.E.N.S. stands for Transcutaneous Electrical Nerve Stimulation. This T.E.N.S. system is used to provide symptomatic pain relief for chronic, acute or post-operative pain.

We do not feel pain until a coded message travels to the brain where it is decoded, analyzed and responded to. The pain message travels from the affected area along small nerve fibers leading into the spinal cord. Here the message is relayed to different nerves that travel up the spinal cord to the brain.

The kind provided to you by your personal Transcutaneous Electrical Nerve Stimulator, TN-28C T.E.N.S. Unit consists of sending small electrical pulses through the skin to the body's nervous system. According to the " gate " theory for pain control, the stimulation of large nerve fibers may result in the blocking of pain transmission.

Features:

- Innovative design
- Large display
- Adjustable frequency
- 5 different modes
- Timer option
- Adjustable pulse width
- Open circuit detectors
- Non-volatile

The intended use of the device:

TN-28C T.E.N.S UNIT is commonly used to provide symptomatic pain relief for chronic, acute or post-operative pain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

EasyMed Instrument Co., Ltd.
c/o Mr. Stefan Preiss
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K040253
Trade/Device Name: EasyMed TN-28C T.E.N.S. Unit
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: March 22, 2004
Received: March 24, 2004

Dear Mr. Preiss:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
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): K040253

Device Name: EasyMed TN-28C T.E.N.S. UNIT

Indications For Use:

T.E.N.S. stands for Transcutaneous Electrical Nerve Stimulation. This T.E.N.S. system is used to provide symptomatic pain relief for chronic, acute or post operative pain.

Prescription Use X 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)

for Mark N Melkerson

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

510(k) Number K040253