K050921

DEC 1 2 2005

510(k) Summary

Date of Summary prepared: January 21, 2005

Submitter: EasyMed Instrument Co., Ltd
Address : No.2 Bei Hai Da Rd Lunjiao, ShunDe, Foshan, Guangdong, China
Tel : +86-757-27727282 27727283
Fax : +86-757-27727868
E-Mail : info@EasyMed.com.cn

Contact person: Frances Lon (Long Shuming)
Jeffery Wu (Wu Tingjie)

Address of the manufacturing facility: The same as above.

Address of American Representative:
Norman F. Estrin, PhD, RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac MD 20854 U.S.A
Tel: 001-301-279-2899
Fax: 001-301-294-0126

Submitted Device:

Generic name: Powered Muscle Stimulator (PMS) (or Electrical Muscle Stimulator (EMS)) and Transcutaneous Electrical Nerve Stimulator (TENS)

Trade name: EasySTIM NMS-28

Common name: For the TENS function—TENS device
For the EMS function—Powered Muscle Stimulators

Classification name: **For TENS functions**
Stimulator, Nerve, Transcutaneous, for Pain Relief - **GZJ;**
21 CFR 882.5890.

For EMS functions
Powered Muscle Stimulator for re-education of muscles - **IPF;**
21 CFR 890.5850

Device Classification: For both TENS & EMS functions - Class **II**

Predicate Device: **For the TENS function**
EasyMed TENS Unit TN-28C (K040253)
For the EMS function
TensCare Ultima NMS/EMS Model XL-A3 - (K023997)

The class of the predicate Device:
Class II

Device Description: **For the TENS function**
A portable TENS device for pain relief.
For the EMS function
A portable EMS device for the re-education of muscles.

Features:

- Innovative design
- Large LCD display
- Dual output channels
- 2 AA Alkaline Batteries
- Adjustable frequency, pulse width, and timing parameters
- 9 different modes
- Timer option
- Doctor lock/unlock facility
- Open circuit detectors
- Non-volatile

The intended use of the device:

1. TENS stands for Transcutaneous Electrical Nerve Stimulation. This TENS system is used to provide symptomatic pain relief for chronic, acute or post-operative pain.

2. For the EMS function, the NMS-28 is used for:
   - Relaxation of muscle spasm
   - Increasing local blood circulation
   - Muscle re-education
   - Prevention or retardation of disuse atrophy

Add: No.2 BeiHai Da Road, LunJiao, ShunDe, GuangDong, China（广东佛山顺德伦教北海大道二号）
Tel: 86-757-27727282 27727283 Fax: 86-757-27727868 Post Code: 528308

•Prevention of venous thrombosis of the calf muscles immediately after surgery
•Maintaining or increasing range of motion

The intended use and indications for use of the new device are the same with that of the predicate devices.

Technological Comparison:

1. The marketed device EasyMed TN-28C (K040253) is a digital TENS unit which has been well exploited the digital technology, supplying the user with full ranges of parameters, traditional TENS functions, and non-traditional new functions to be selected.

2. In assembly, except software, the new device NMS-28 is exactly the same with the marketed device TN-28C, they have the same enclosure, the same circuit diagram, the same PCB layout, the same components and the same working principle;

3. The marketed device TensCare Ultima NMS/EMS Model XL-A3 - (K023997) combines the functions of a TENS device and an EMS (Electrical Muscle Stimulator) or Powered Muscle Stimulator, into one package. It is also a digital unit with similar electronic working principle with TN-28C.

4. The new device NMS-28 also combines the functions of a TENS device and an EMS into one package. It is also substantial equivalent to the marketed device TensCare Ultima NMS/EMS Model XL-A3 - (K023997), their features and performances in muscle controlling as well as pain relief therapy are very similar substantially.

5. The software of the new device NMS-28 can be divided into two parts: one for TENS function, the another for EMS function. The part of software for TENS function of the new device NMS-28 is only a subset of that of the marketed device TN-28C, what is more, the considerations on safety and reliability in TN-28C are also introduced into the EMS function of the new device; While the part of software for EMS function of the new device NMS-28 is very similar to that of the marketed device TensCare Ultima NMS/EMS Model XL-A3, by applying the similar control methods for muscle contraction-relaxation.

6. The accessories of the new device NMS-28 are almost the same

Add: No.2 BeiHai Da Road, LunJiao, ShunDe, GuangDong, China（广东佛山顺德伦教北海大道二号）
Tel: 86-757-27727282 27727283 Fax: 86-757-27727868 Post Code: 528308

with those of the marketed device TN-28C, and substantially equivalent to marketed device TensCare Ultima NMS/EMS Model XL-A3.

Labeling Comparison: The Labeling is substantially equivalent to that of the predicate devices.

Safety information:

Design to comply with relevant safety applicable recognized consensus standards; the output energy is well controlled in the safety and effectiveness ranges specified by relevant FDA guidance's. Testing has been carried out in very detailed and strict. Test results, Risk Analysis, and FMEA analysis show that the new unit NMS-28 is safe with no any hazard.

NMS-28 combines the functions of TENS and EMS into one package, it is not possible to use the TENS and the EMS functions simultaneously. Mechanical integrity ensures that only one function can be selected at any one time.

NMS-28 has been on the European Market for the past two years. During this time a review of Customer Complaints, Returned Product and the results of Post Market Feedback, has demonstrated that the product has performed as Intended, to it's Specified Requirements.

Submitted times: It is the first submission to FDA for this new device

Conclusions: The NMS-28 EMS/TENS unit is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

Add: No.2 BeiHai Da Road, LunJiao, ShunDe, GuangDong, China (广东佛山顺德伦教北海大道二号)
Tel: 86-757-27727282 27727283 Fax: 86-757-27727868 Post Code: 528308

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2005

Jeffrey Wu
EasyMed Instrument Co., Ltd
No. 2 Bei Hai Da Road
LunJiao, ShunDe
Guangdong, China

Re: K050921
Trade/Device Name: EasyMed EMS/TENS Model NMS-28
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Codes: IPF, GZJ
Dated: June 17, 2005
Received: November 23, 2005

Dear Mr. Wu:

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 (240) 276-0120. 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 Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number : K050921

Device Name : EasyMed EMS/TENS Model NMS-28

Indications for Use :

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

PMS/EMS stands for Powered Muscles Stimulator/Electrical Muscles Stimulator. This PMS/EMS system is indicated for:

- Relaxation of muscle spasm
- Increasing local blood circulation
- Muscle re-education
- Prevention or retardation of disuse atrophy
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increasing range of motion

Prescription Use___X___ 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)

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

510(k) Number K050921