K120054

JUN - 5 2012

510(k) Summary

Date of Summary prepared: 31 December 2011

Submitter: Pain Management Technologies
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Address of the manufacturing facility:
EasyMed Instruments Co., Ltd
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Submitted Device:

Generic name: Powered Muscle Stimulator (PMS) (or Electrical Muscle Stimulator (EMS)), Transcutaneous Electrical Nerve Stimulator (TENS), Microcurrent (MIC) TENS stimulator and Interferential Current Therapy Stimulator (IF)

Trade name: Ultima NEO

Common name: For the TENS/MIC system—TENS device
For the EMS system—Powered Muscle Stimulators
For the IF system—Interferential Stimulator

Classification name: **For EMS system**
Powered Muscle Stimulator for re-education of muscles - **IPF;**
21 CFR 890.5850

For TENS / MIC system
Stimulator, Nerve, Transcutaneous, for Pain Relief - **GZJ;**
21 CFR 882.5890.

For IF system
Interferential current therapy – **LIH**

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Device Classification: For EMS, TENS / MIC and IF systems - Class II

Predicate Devices: EasyMed EMS/TENS Model NMS-28 (K050921);
MT9000 Combo TENS/EMS/IF/MIC (K093138)/(Trade name : InTENSity™ Select Combo) ;
GM3 Series IF TENS Model GM3X2IF (K032719)

The class of the predicate Devices:
Class II

Device Description: A portable TENS/EMS/MIC/IF combo device for pain relief or muscle re-education.

Features:

- Innovative design
- Large LCD display
- Dual output isolated channels
- One rechargeable lithium battery
- Adjustable frequency, pulse width, and timing parameters
- 18 different modes
- Timer option
- Doctor lock/unlock facility
- Open circuit detectors
- Non-volatile

The intended use of the device:

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

EMS stands for Electrical Neuromuscular Stimulator. The Ultima NEO EMS system is indicated for:

- Relaxation of muscle spasm;
- Increasing local blood circulation and 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.

MIC stands for Microcurrent Stimulation. The Ultima NEO MIC system is used to provide symptomatic pain relief for chronic intractable pain, post traumatic pain or post surgical pain.

IF stands for Interferential Stimulation. The Ultima NEO IF system is indicated for:

- Symptomatic relief of chronic intractable pain.

The intended use and indications for use of the new device are very similar to that of the predicate devices.

Technological Comparison:

1. The new device Ultima NEO is a portable electrotherapy device which combines four systems : Transcutaneous Electrical Nerve Stimulation (TENS), Electrical Muscle Stimulation (EMS), Microcurrent (MIC) and Interferential (IF), into one enclosure. These four systems work separately. When one system is working, the others do not work and thus do not affected each other. This feature has been fully guaranteed by the design.

2. The marketed device EasyMed EMS/TENS Model NMS-28 (K050921) combines the systems of a TENS and an EMS (Electrical Muscle Stimulator or Powered Muscle Stimulator), into one package. It is a digital TENS/EMS combo unit which has been well exploited the digital technology, supplying the user preset programs and manual selectable programs with full ranges of parameters.

3. The new device Ultima NEO also combines the systems of TENS and EMS into one package. It is also substantial equivalent to the marketed device EasyMed EMS/TENS Model NMS-28 (K050921), their features and performances in muscle controlling as well as pain relief therapy are almost the same substantially.

4. The designed circuitry of TENS and EMS modes in the new device Ultima NEO is almost the same as the marketed device EasyMed EMS/TENS Model NMS-28 (K050921). For the TENS and EMS systems, they are of almost the same circuit diagrams and same working principle; The main difference between the two devices is that the new device Ultima NEO is also combined the Microcurrent (MIC) and Interferential (IF) systems into one package. But these systems are worked separately.

5. The marketed device MT9000 Combo TENS/EMS/IF/MIC (K093138) is a combo device which includes the Microcurrent stimulation system. The Microcurrent stimulation can be generated by a very low and relatively long period current. The specification of

microcurrent system in MT9000 Combo TENS/EMS/IF/MIC K093138 is very similar to that of Ultima NEO MIC system.

6. The marketed device GM3 Series IF TENS Model GM3X2IF (K032719) is an interferential stimulator which generates the real-sine waves of electrical current. The specification of GM3X2IF (K032719) is very similar to that of Ultima NEO IF system.

7. The new device Ultima NEO is designed and combined the Interferential (IF) and Microcurrent (MIC) systems based on the design of EasyMed EMS/TENS Model NMS-28 (K050921). The introduction of marketed device GM3 Series IF TENS Model GM3X2IF (K032719) and MT9000 Combo TENS/EMS/IF/MIC (K093138) are for the purpose of comparison of the feature of Microcurrent (MIC) and Interferential (IF).

8. The new device Ultima NEO is of the same ranges of parameters as those of marketed devices.

9. The software of the new device Ultima NEO can be divided into four parts: the first for TENS system, the second for EMS system, the third for MIC system, and the four one for IF system. First of all, the part of software for TENS system of the new device Ultima NEO is only a subset of that of the marketed device EasyMed EMS/TENS Model NMS-28 (K050921). Secondly, the considerations on safety, effectiveness and reliability in NMS-28 (K050921) are also introduced into the EMS system of the new device; While the part of software for EMS system of the new device Ultima NEO is almost the same as that of the marketed device EasyMed EMS/TENS Model NMS-28 (K050921), by applying almost the same control methods for muscle contraction-relaxation. In other word, the TENS and EMS systems of the new device Ultima NEO are almost the same as those of the marketed device NMS-28 (K050921). Thirdly, the part of software for Microcurrent (MIC) system of the new device Ultima NEO is very similar to that of the marketed device MT9000 Combo TENS/EMS/IF/MIC (K093138). For the last, the part of software for Interferential (IF) system of the new device Ultima NEO is very similar to that of the marketed device GM3 Series IF TENS Model GM3X2IF (K032719)

10. Both the new device Ultima NEO and the marketed devices

NMS-28 (K050921)/ GM3 Series IF TENS Model GM3X2IF (K032719)/ MT9000 Combo TENS/EMS/IF/MIC (K093138) are passed the same tests of applicable recognized international consensus standards.

11. The accessories of the new device Ultima NEO are similar to those of the marketed devices.

Labeling Comparison: The Labelling 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 strictly. Test results and Risk Analysis show that the new unit Ultima NEO is safe with no any hazard.

Ultima NEO combines the systems of TENS, EMS, Micocurrent, and IF into one package, it is not possible to use any other system(s) simultaneously when one system is being used. Mechanical and electronical integrity ensures that only one system can be selected at any one time.

Standard ORG	Standard Number	Standard Title
IEC	60601	Medical Electrical equipment- Part I:
IEC	6060I - I -2	Medical Electrical equipment- Part I-2:
IEC	6060I-1-4	Medical Electrical equipment- Part I-4:
IEC	60601-2-10	Medical electrical equipment Part2 -10:
ISO	14971	Medical devices-
ISO	I 3485	Medical Devices- Quality Management systems-
IC council	93/42/EEC	EC Directive 93/42/EEC Annex V, Article 3,
IEC/EN	62304	IEC 62304 Ed. 1.0, Medical device software

IEC-EN	6060I-I-6	Medical electrical equipment .Part I-6:
ISO	9001	Quality management systems-
UL	6060I-I	Medical electrical equipment Part I :

Conclusions:

The new device Ultima NEO, which includes TENS, EMS, MICrocurrent, and IF systems, has the same intended use and technological characteristics as the predicate devices of NMS-28 (K050921)/ MT9000 Combo TENS/EMS/IF/MIC (K093138) /GM3 Series IF TENS Model GM3X2IF (K032719). Thus, the new device Ultima NEO is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

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

Pain Management Technologies
c/o Mr. Joshua Lefkovitz
President
1340 Home Avenue, Building A
Akron, OH 44310

JUN - 5 2012

Re: K120054
Trade/Device Name: Ultima NEO
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, IPF, LIH
Dated: May 18, 2012
Received: May 24, 2012

Dear Mr. Lefkovitz:

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,

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

510(k) Number : K120054

Device Name : Ultima NEO

Indications for Use

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

EMS stands for Electrical Neuromuscular Stimulator. The Ultima NEO EMS system is indicated for:

- Relaxation of muscle spasm;
- Increasing local blood circulation and 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.

MIC stands for Microcurrent Stimulation. The Ultima NEO MIC system is used to provide symptomatic pain relief for chronic intractable pain, post traumatic pain or post surgical pain.

IF stands for Interferential Stimulation. The Ultima NEO IF system is indicated for:

- Symptomatic relief of chronic intractable pain.

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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K120054