K032720

DEC 1 0 2003

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

1. Submitter's Identifications:
   GEMORE TECHNOLOGY CO., LTD.
   11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD.,
   Tan Shui, Taipei Hsien, Taiwan

   Contact:
   Boden S.P. Lai
   General Manager

   Date of Summary Preparation: August 29,2003.

2. Name of the Device:
   GEM-STIM TENS/Model GM3XY and GM3AXY where "X" is parameter for different outlook which may be different from 0~5. "Y" is parameter for different operation type, which may be different with the parameter of "0T", "0E", "0PP", "0PE", and "0TE".

3. Information of the 510(k) Cleared Device (Predicate Device): K021359 & K020314.

4. Device Description:

   The GEM-STIM TENS series, including GM3X0T/GM3AX0T, GM3X0E/GM3AX0E, GM3X0PP/GM3AX0PP, GM3X0PE/GM3AX0PE, and GM3X0TE/GM3AX0TE are transcutaneous electrical nerve stimulator used for pain relief and/or powered muscle stimulator by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the situation of patient.

   GEM-STIM TENS series, models GM3X0T/GM3AX0T, GM3X0E/GM3AX0E, GM3X0PP/GM3AX0PP, GM3X0PE/GM3AX0PE, and GM3X0TE/GM3AX0TE, consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the patient's skin so as to transmit this stimulus current to the patient for pain relief.

   The stimulation mode for GEM-STIM TENS includes several different operation modes as mentioned on the comparison table. These operation modes are generated from the software control by using the microprocessor as its main control unit.

5. Intended Use:

   On the instruction manual of each model, the intended uses and contraindication are defined very clearly. Please see the information of instruction manuals in clause 7.6 of this submission document.

   In addition, the standard format for the statement of indications and contraindication for use are provided hereafter.

ATTACHMENT 3-1

510(k) Number (if known): K032720

Device Name: GEM-STIM TENS/Model GM3XY and GM3AXY where "X" is parameter for different outlook, "X" may be different from 0~5, "Y" is parameter for different operation type, "Y" may be different with one of the following parameters, '0T', '0E', '0PP', '0PE' and '0TE'.

Indications For Use (Available for GM3X0T/GM3AX0T, GM3X0PP/GM3AX0PP, and TENS function of GM3X0TE/GM3AX0TE):

This device is a prescription device and only for symptomatic relief of chronic intractable pain.

Indications For Use (Available for GM3X0E/GM3AX0E, & 'EMS function' of GM3X0TE/GM3AX0TE):

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

Indications For Use (Available for GM3X0PE/GM3AX0PE):

- Relaxation of muscle spasms.

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6. Comparison to the 510(k) Cleared Device (Predicate Device):

(1) The new model GM3X0T/GM3AX0T and GM3X0PP/GM3AX0PP are substantially equivalent to the Well-Life clear model WL-2203 (K021359).
(2) The new model GM3X0E/GM3AX0E, GM3X0PE/GM3AX0PE are substantially equivalent to the Well-Life clear model WL-2204 (K020314).
(3) The new model GM3X0TE/GM3AX0TE is substantially equivalent to the Well-Life clear model WL-2205 (K021359 & K020314).

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

8. Conclusions
The GEM-STIM TENS series, including GM3X0T/GM3AX0T, GM3X0E/GM3AX0E, GM3X0PP/GM3AX0PP, GM3X0PE/GM3AX0PE, and GM3X0TE/GM3AX0TE, have the same intended use and technological characteristics as the cleared device of WL-2203, WL-2204, and WL-2205. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2003

Mr. Boden S.P. Lai
General Manager
Gemore Technology Co., Ltd.
11FL., No. 29-5, Sec. 2, Chung Cheng E. RD.,
Tan Shui, Taipei Hsien, Taiwan

Re: K032720

Trade/Device Name: GEM-STIM Models GM3X0T, GM3AX0T, GM3X0PP, and GM3AX0PP
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ

Trade/Device Name: GEM-STIM Models GM3X0E, GMAX0E, GM3X0PE, and GM3X0PE
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF

Trade/Device Name: GEM-STIM Models GM3X0TE and GM3AX0TE
Regulation Numbers: 21 CFR 890.5850, 21 CFR 882.5890
Regulation Names: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: IPF, GZJ

Dated: July 21, 2003
Received: September 12, 2003

Dear Mr. Lai:

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.

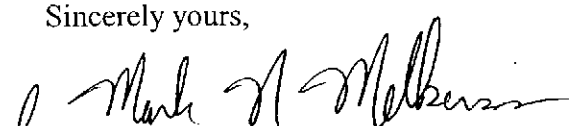
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the
Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

GEMORE TECHNOLOGY CO., LTD.

ATTACHMENT 3-1

510(k) Number (if known): K032720

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Indications For Use (Available for GM3X0T/GM3AX0T, GM3X0PP/GM3AX0PP, and TENS function of GM3X0TE/GM3AX0TE):

This device is a prescription device and only for symptomatic relief of chronic intractable pain.

Indications For Use (Available for GM3X0E/GM3AX0E, & 'EMS function' of GM3X0TE/GM3AX0TE):

- Relaxation of muscle spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Muscle re-education.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.

Indications For Use (Available for GM3X0PE/GM3AX0PE):

- Relaxation of muscle spasms.

Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Division Sign-Off
Division of General, Restorative
Devices

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