JUL 2 0 2012

## 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: K120569 .

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 / President & Official Correspondent
Phone Number:886-2-8809-1799
Fax Number:886-2-8809-1781

Date of Summary Preparation: July 12, 2012.

2. Name of the Device:

| | |
|---|---|
| Trade name: | GEMORE TENS System; models GM310TP/ GM320TP/ GM330TP/GM340TP |
| Common name: | Stimulator, Nerve, Transcutaneous For Pain Relief. |
| Classification name: | Stimulator, Nerve, Transcutaneous For Pain Relief. |
| Product Code: | GZJ & NYN |

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

For this 510(k) submission, we compared our models to the following FDA cleared TENS devices:
- K061650: Empi – SELECT TENS System.

4. Device Description:

The Gemore TENS System / Model GM310TP, GM320TP, GM330TP, and GM340TP transcutaneous electrical nerve stimulators for pain relief, are the electrically power devices used to apply an electrical current to electrode on a patient's skin to relieve pain. This series of TENS devices are indicated for:

- symptomatic relief of chronic, intractable pain
- adjunctive treatment for post-surgical and post-traumatic acute pain
- relief of pain associated with osteoarthritis of the knee and rheumatoid arthritis of the hand

For this definition of intended use, the Gemore TENS system is classified with the "NYN" & "GZJ" product code under 21CFR/Part 882.5890 FDA regulation classification number.

The Gemore TENS system consists mainly of two parts: the stimulus generator and electrode. The stimulus generator generates the output current specified as the input of controller. The output of controller is able to be adjusted for B/C/M/P1/P2/P3/P4/P5 eight operation modes which bear different combination for the output parameters of pulse width, pulse rate, and pulse cycle. For every operation mode, the operator could adjust output intensity, pulse width, pulse rate and operation time. The output parts transmit the output current to the electrodes which is attached to the patient's skin so as to transmit the generated stimulus to patient for pain relief treatment.

GM310TP/GM320TP/GM330TP/GM340TP is completely identical to that of model as mentioned in our previous submission of GEM STIM TENS, model GM310TE/ GM320TE/GM330TE/GM340TE (K032720). To change the indication for use as that of the chosen predicate devices, Gemore changed the software for these four models.

For the device included in this submission, we use the following of our 510(K) legally marketed predicate garment electrodes:

<1>K062675, "Gemore Reuseable Self Adhesive Electrode" ; Wire Series/ Model FA5050 ( 5x5 CM or bigger size) self adhesive electrode.

GM310TP/GM320TP/GM330TP/GM340TP is a selectable dual channel, 9V battery operated TENS device with the following features:

<1> The operation function is dual channels completely identical to the model being modified, GM310TE/GM320TE/GM330TE/GM340TE (K032720).

<2> The output of controller is able to be adjusted for B/C/M/P1/P2/P3/P4/P5 eight operation modes which bear different combination for the output parameters of pulse width, pulse rate, and pulse cycle.

<3> The output strength is adjustable at 0~80 mA, with maximum setting time 60 minutes counting from switching ON.

<4> The LCD display is provided for the indication of operation status including CH1/CH2, output program mode, pulse width, pulse rate, timer, and battery low warning

5. Intended Use:

The indication for use is defined by the following statement:

The GEMORE TENS System, model GM310TP/GM320TP/GM330TP/GM340TP Transcutaneous Electrical Nerve Stimulators are indicated for:

- symptomatic relief of chronic, intractable pain
- adjunctive treatment for post-surgical and post-traumatic acute pain
- relief of pain associated with osteoarthritis of the knee and rheumatoid arthritis of the hand

6. 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 IEC 60601-1, and IEC 60601-1-2 requirement. In addition to compliance of the voluntary standards, the software verification has been carried out in accordance to the FDA software guidance.

7. Similarities and differences comparison:

For the similarities and differences comparison between the application model GM310TP/ GM320TP/GM330TP/GM340TP and predicate 510(K) cleared model, the Emip-select TENS System, please see the details of the following table:

| Comparison features | Gemore Model | Predicate 510(K) cleared Model |
|---|---|---|
| Model Name | GEMORE TENS System, model GM310TP/ GM320TP/ GM330TP/ GM340TP | Emip-Select TENS System |
| 510(K) number | K120569 | K061650 |
| Indication for use | indicated for:<br>• symptomatic relief of chronic, intractable pain<br>• adjunctive treatment for post-surgical and post-traumatic acute pain<br>• relief of pain associated with osteoarthritis of the knee and rheumatoid arthritis of the hand | used for the symptomatic relief and management of chronic, intractable pain and pain associated with arthritis. They are also used as an adjunctive treatment for post-surgical and post-trauma acute pain |
| Product Code | GZJ & NYN | Same |
| Program mode | B/C/M and P1~P5 pre-program mode (Note: The program mode is similar to predicate device) | B/C/M & ARB/SMP/MA/SPM preprogram mode |
| Conformance standards | IEC 60601-1<br>IEC 60601-1-2<br>ANSI/AAMI NS4 | IEC 60601-1<br>IEC 60601-1-2 |
| Outlook & Dimensions | 108x61.5x25 mm | 109.5x60x34.9 mm |
| Weight | 140 g | 138.9 g |

8. Comparision for the basic unit characteristics : As the following table

| Parameter | | New Device | Predicate Device |
|---|---|---|---|
| 510(K) Number | | K120569 | K061650 |
| Device Name and Model | | GEMORE TENS System | SELECT TENS System |
| Manufacturer | | Gemore | Empi |
| Power Source(s) | | 9V battery | 1.5Vx2 (AA Size) |
| - Method of Line current Isolation | | Type BF | Same |
| - Patient Leakage Current | | --- | --- |
| - Normal condition ($u$A) | | Under 0.1 | Same |
| - single Fault condition ($u$A) | | Under 0.5 | Same |
| Average DC current through electrodes when device is on but no pulses are being applied ($u$A) | | Not applicable | Same |
| Number of Output Modes | | 2 | Same |
| Number of Output Channels: | Synchronous or Alternating? | Synchronous | Same |
| | Method of Channel Isolation | Output transformer | Same |
| Regulated Current or Regulated Voltage? | | Current | Same |
| Software/Firmware/Microprocessor control? | | Yes | Same |
| Automatic Overload Trip? | | No | Same |
| Automatic No-Load Trip? | | No | Same |
| Automatic Shut Off? | | Yes | Same |
| User Override control? | | No | Same |
| Indicator Display: | On/Off Status? | Yes | Same |
| | Low Battery? | Yes | Same |
| | Voltage/Current Level? | No | Same |
| Timer Range (Minutes) | | 15,30, and 60 | 1~60 |
| Compliance with Voluntary Standards? | | IEC 60601-1<br>IEC 60601-1-2<br>ANSI/AAMI NS4. | IEC 60601-1<br>IEC 60601-1-2 |
| Compliance with 21 CFR 898? | | Yes | Same |
| Weight (g) | | 140 | 138.9 |
| Dimensions (mm.) [W x H x D] | | 108x61.5x25 | 109.5x60.3x34.9 |
| Housing Materials and construction | | ABS | Same |

9. Comparison of Output Specification : As the following table

Maximum output specification:

| Parameter | | Your Device | | Predicate Device | |
|---|---|---|---|---|---|
| Mode or Program Name | | GM320TP as representative | | SELECT TENS System | |
| Waveform (e.g., pulsed monophasic, biphasic) | | Monophasic | | Same | |
| Shape (e.g., rectangular, spike, rectified sinusoidal) | | Rectangular | | Same | |
| Maximum Output Voltage (volts) (+/- 20 %) | | 40V | @500Ω | 26V | @500Ω |
| | | 96V | @2k Ω | 40V | @2k Ω |
| | | 110V | @10k Ω | 40V | @10k Ω |
| Maximum Output Current (specify units) (+/- 20 %) | | 80mA | @500Ω | 52mA | @500Ω |
| | | 48mA | @2k Ω | 20mA | @2k Ω |
| | | 11mA | @10k Ω | 4mA | @10k Ω |
| Duration of primary (depolarizing) phase (usec) | | 260 (usec) Max | | 400 (usec) Max | |
| Pulse Duration (usec) | | 260 Max | | 400 Max | |
| Frequency (Hz) [or Rate (pps)] | | 160 Max | | 150 Max | |
| For multiphasic waveforms only: | Symmetrical phases? | No | | Same | |
| | Phase Duration (include units), (Stage range, if applicable), (both phases, if asymmetrical) | Not Applicable | | Same | |

Detailed comparison for each operation mode:

| Max Phase Charge | | Max Current Density | | Max Avg Current | | Max Power Density | | Operation Mode |
|---|---|---|---|---|---|---|---|---|
| Gemore | Emip | Gemore | Emip | Gemore | Emip | Gemore | Emip | |
| 20.8uQ | 20.8uQ | 0.083 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 2.08 mA | 3.12 mA | 0.0033 w/ cm$^2$ | 0.0037 w/ cm$^2$ | B |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | C |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | M |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | P1 |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | P2 |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | P3 |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | P4 |
| 20.8uQ | 20.8uQ | 0.133 mA/cm$^2$ | 0.1248 mA/cm$^2$ | 3.328 mA | 3.12 mA | 0.0053 w/ cm$^2$ | 0.0037 w/ cm$^2$ | P5 |

10. Conclusions

The GEMORE TENS System, model GM310TP/GM320TP/GM330TP/GM340TP have the same technological characteristics as the of the 510(K) cleared device, the Empi – SELECT TENS System. (K061650). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted model 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. Therefore, the GEMORE TENS System, model GM310TP/GM320TP/GM330TP/GM340TP are substantial equivalent to the chosen predicate model.

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

GEMORE TECHNOLOGY CO., LTD.
c/o Mr. Boden S.P. Lai
General Manager
11 FL. No. 29-5, Sec. 2
Chung Cheng E. Rd.
Tan Shui, Taipei Hsien
Taiwan 251

JUL 20 2012

Re: K120569
Trade/Device Name: GEMORE TENS System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ, NYN
Dated: July 13, 2012
Received: July 16, 2012

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. 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

# Indications For Use

510(k) Number (if known): K120569

Device Name: GEMORE TENS System, model GM310TP/GM320TP/ GM330TP/GM340TP

Indications For Use:

The GEMORE TENS System, model GM310TP/GM320TP/GM330TP/GM340TP Transcutaneous Electrical Nerve Stimulators are indicated for:

- symptomatic relief of chronic, intractable pain
- adjunctive treatment for post-surgical and post-traumatic acute pain
- relief of pain associated with osteoarthritis of the knee and rheumatoid arthritis of the hand

Prescription Use √ 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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Numb K120569