510(K) Summary

DEC 2 1 2012

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 on August 30, 2012.

The assigned 510(k) number is: k122944.

1. Submitter 's Identifications:

Company Name :	GEMORE TECHNOLOGY CO., LTD.
Contact person:	Boden S.P. Lai
Address :	11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD., Tan Shui, Taipei Hsien, Taiwan
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E-mail address :	**boden001@gmail.com**

2. Name of the Device:

Trade/Device Name: Gemore IF True Sine Interferential Stimulator
Model GM3A00IF/GM3A10IF/GM3A20IF/GM3A50IF
Regulation Number: Unclassified
Regulation Name: Interferential Stimulator
Regulatory Class: II
Product Code: LIH

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

Gemore IF TENS/Model: GM322IF(K032719).

4. Dev ice Description:

The Gemore IF series True sine interferential stimulator / Model: GM3A00IF/GM3A10IF/ GM3A20IF/GM3A50IF are the device which generates the small true-sine pulses of electrical current. The generated current may be delivered to the patient skin and/or underlying nerves through the cable and electrode placed on skin.

5. Intended Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

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

6. Subst antial Equivalence Comparison

The Gemore IF series True sine interferential stimulator / Model: GM3A00IF/GM3A10IF/ GM3A20IF/GM3A50IF have output characteristics and controls that are identical to those of the predicate device. The new devices were modified different from the predicate device with the following different features:

1> The new device housing was designed and constructed for each model.
2> The firmware, software and operation interface were change so as to change the operation type from digital to analog.
3.> The maximum intensity adjustment range was changed from 60mA to 70 mA.
4> The operation modes was reduced from 9 modes into 4 modes.

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 IEC 60601-1, and IEC 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 Gemore IF true sine interferential stimulator, model GM3A00IF/GM3A10IF/GM3A20IF /GM3A50IF, has the same intended use and technological characteristics as the cleared device of GM322IF(K032719). 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2012

Gemore Technology Company, Ltd.
% Mr. Boden S. P. Lai
General Manager
11 Fl, No. 29-5, Sec 2
Chung Cheng E. Rd
Tan Shui, Taipei Hsien
China (Taiwan) 251

Re: K122944
Trade/Device Name: Gemore IF series True sine interferential stimulator/Model GM3A00IF/GM3A10IF/GM3A20IF/GM3A50IF
Regulation Number: Unclassified
Regulation Name: Interferential Stimulator
Regulatory Class: Class II
Product Code: LIH
Dated: September 21, 2012
Received: September 24, 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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K122944

Device Name: Gemore IF series True sine interferential stimulator
Model: GM3A00IF/GM3A10IF/GM3A20IF/GM3A50IF.

Indications For Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-The-Counter Use ___

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K122944