August 16, 2019

Gemore Technology Co Ltd
Boden Lai
Official Correspondent
11FL., No.29-5, Sec.2, Chug Cheng E. RD.,
Tan Shui, New Taipei City, 251 Tw

Re: K190988
Trade/Device Name: GEM-STIM OTC TENS/EMS System Models: GM510, GM511, GM520, GN530, GM540
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN
Dated: May 15, 2019
Received: May 17, 2019

Dear Boden 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K190988

Device Name: GEM-STIM OTC TENS/EMS System, model GM511TE/GM511T/GM511E
(where “T” means the device with TENS function only, “E” means the device with EMS function only, and “TE” means the device with both TENS & EMS function.)

Indications For Use:

GM511TE & GM511T- for temporary relief of pain associated with sore and aching muscles in the lower back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P9 or P17 to P19 and C/B/M/H1/H2 adjustable mode)

GM511TE & GM511T- for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (including osteoarthritis and rheumatoid arthritis). It is also used as an adjunctive treatment for post-surgical and post-traumatic acute pain. (Choose TENS Mode P10)

GM511TE & GM511E - for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P11 to P16 and C/S/A adjustable mode)

Prescription Use _____ 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)

Indications For Use

510(k) Number (if known): K190988

Device Name: GEM-STIM OTC TENS/EMS System, model GM510TE/GM510T/GM510E
(where “T” means the device with TENS function only, “E” means the device with EMS function only, and “TE” means the device with both TENS & EMS function.)

Indications For Use:

GM510TE & GM510T- for temporary relief of pain associated with sore and aching muscles in the lower back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P9 or P17 to P19)

GM510TE & GM510T- for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (including osteoarthritis and rheumatoid arthritis). It is also used as an adjunctive treatment for post-surgical and post-traumatic acute pain. (Choose TENS Mode P10)

GM510TE & GM510E - for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P11 to P16)

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)

Indications For Use

510(k) Number (if known): K190988

Device Name: GEM-STIM OTC TENS/EMS System, model GM520TE/GM520T/GM520E
(where “T” means the device with TENS function only, “E” means the device with EMS function only, and “TE” means the device with both TENS & EMS function.)

Indications For Use:

GM520TE & GM520T- for temporary relief of pain associated with sore and aching muscles in the lower back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P9 or P17 to P19)

GM520TE & GM520T- for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (including osteoarthritis and rheumatoid arthritis). It is also used as an adjunctive treatment for post-surgical and post-traumatic acute pain. (Choose TENS Mode P10)

GM520TE & GM520E - for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P11 to P16)

Prescription Use _____ 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)

Indications For Use

510(k) Number (if known): K190988

Device Name: GEM-STIM OTC TENS/EMS System, model GM530TE/GM530T/GM530E
(where “T” means the device with TENS function only, “E” means the device with EMS function only, and “TE” means the device with both TENS & EMS function.)

Indications For Use:

GM530TE & GM530T- for temporary relief of pain associated with sore and aching muscles in the lower back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P9 or P17 to P19)

GM530TE & GM530T- for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (including osteoarthritis and rheumatoid arthritis). It is also used as an adjunctive treatment for post-surgical and post-traumatic acute pain. (Choose TENS Mode P10)

GM530TE & GM530E - for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes P11 to P16)

Prescription Use _____ 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)

Indications For Use

510(k) Number (if known): K190988

Device Name: GEM-STIM OTC TENS/EMS System, model GM540TE/GM540T/GM540E
(where “T” means the device with TENS function only, “E” means the device with EMS function only, and “TE” means the device with both TENS & EMS function.)

Indications For Use:

GM540TE & GM540T- for temporary relief of pain associated with sore and aching muscles in the lower back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes P1 to P9 or P17 to P19)

GM540TE & GM540T- for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis (including osteoarthritis and rheumatoid arthritis). It is also used as an adjunctive treatment for post-surgical and post-traumatic acute pain. (Choose TENS Mode P10)

GM540TE & GM540E - for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. (ChooseEMS Modes P11 to P16)

Prescription Use _____ 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)