



February 12, 2024

Chongqing Rob Linka Science and Technology Co., Ltd.
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K233092

Trade/Device Name: Pain Therapy Device (SM9075, SM9910, SM9067, SM9587W)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN, GZJ, IPF
Dated: January 12, 2024
Received: January 12, 2024

Dear Cassie Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

 Robert Kang -S

for Pamela Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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

Submission Number (if known)

K233092

Device Name

Pain Therapy Device (SM9075, SM9910, SM9067, SM9587W)

Indications for Use (Describe)

For Over-The-Counter Use:

TENS:

SM9075 (mode 1-24), SM9910 (mode 1-8), SM9067 (mode 1-9), SM9587W (mode 1-8) are used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

SM9075 (mode 1-24), SM9910 (mode 1-8), SM9067 (mode 1-9), SM9587W (mode 1-8) are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS/NMES:

SM9075 (mode 25-48, 49-60), SM9910 (mode 9-16, 17-24), SM9067 (mode 10-18, 19-36), SM9587W (mode 9-18, 19-24) are used to stimulate healthy muscles in order to improve and facilitate muscle performance.

To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

SM9075 (mode 25-48), SM9910 (mode 9-16), SM9067 (mode 10-18), SM9587W (mode 9-18) are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

For Prescription Use:

TENS:

SM9075 (mode 1-24), SM9910 (mode 1-8), SM9067 (mode 1-9), SM9587W (mode 1-8) are intended for the following use:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

PMS/NMES:

SM9075 (mode 25-48, 49-60), SM9910 (mode 9-16, 17-24), SM9067 (mode 10-18, 19-36), SM9587W (mode 9-18, 19-24) are intended for the following use:

- Temporary relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Increase of local blood flow in the treatment area
- Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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