



November 1, 2021

Guangzhou Xinbo Electronic Co., Ltd.
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 511400
China

Re: K212948

Trade/Device Name: Pain Therapy Device(Model: DH-P.T.S-I, DH-P.T.S-II, DH-P.T.S-IIA, DH-P.T.S-IIB, DH-CP-I)

Regulation Number: 21 CFR 890.5850

Regulation Name: Powered Muscle Stimulator

Regulatory Class: Class II

Product Code: NGX, NUH, IPF, NYN, GZJ

Dated: September 14, 2021

Received: September 16, 2021

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 (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,

For Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)

K212948

Device Name

The Pain Therapy Device (Model: DH-P.T.S-I, DH-P.T.S-II, DH-P.T.S-IIA, DH-P.T.S-IIB, DH-CP-I)

Indications for Use (Describe)

The Pain Therapy Device (Model: DH-P.T.S-I, DH-P.T.S-II, DH-P.T.S-IIA, DH-P.T.S-IIB, DH-CP-I):

TENS:

- For relief of pain and management of pain associated with sore and aching muscles in the upper and lower back, back of the neck, upper extremities (shoulder and arm), lower extremities (leg and feet) due to strain from exercise, work or normal household work activities by applying transcutaneous electrical current to stimulate the nerves.
- For relief of pain associated with arthritis.
- For symptomatic relief and management of chronic intractable pain

EMS:

- To stimulate healthy muscles in order to improve and facilitate muscle performance.
- To temporarily increase local blood circulation in healthy muscles.

NMES:

- For relaxation of muscle spasm.
- Increase of blood flow circulation.
- Prevention or retardation of disuse muscle atrophy.
- Muscle re-education.
- Maintaining or increasing range of motion.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- For Users with conditions or diseases that are associated with impaired (poor) blood flow in the legs/ankle/feet. NMES through the foot electrodes is intended to use as an adjunctive treatment (as an additional treatment to your existing treatment) to temporarily reduce lower extremity pain, swelling and cramping.

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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