August 3, 2020

TheraSigma, LLC
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K201958
Trade/Device Name: ETD Family of Electrotherapy Devices: Models ETD100, ETD200, ETD300, ETD400, ETD500, ETD600, and ETD700
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, LIH, GZJ
Dated: July 3, 2020
Received: July 14, 2020

Dear Rafael Aguila:

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,

Vivek Pinto, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201958

Device Name
ETD Family of Electrotherapy Devices: Models ETD100, ETD200, ETD300, ETD400, ETD500, ETD600, and ETD700

Indications for Use *(Describe)*

ETD100 TENS Device
TENS Mode: Transcutaneous Electrical Nerve Stimulation for Pain Relief: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.

ETD200 NMES Device
NMES Mode: Neuromuscular Electrical Stimulation: Relaxation of muscle spasm, increasing local blood circulation, maintaining and increasing range of motion, preventing or retarding muscle disuse atrophy, muscle reeducation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

ETD300 TENS and NMES Combination Device
TENS Mode: Transcutaneous Electrical Nerve Stimulation for Pain Relief: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.
NMES Mode: Neuromuscular Electrical Stimulation: Relaxation of muscle spasm, increasing local blood circulation, maintaining and increasing range of motion, preventing or retarding muscle disuse atrophy, muscle reeducation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

ETD400 IFCS Device (IFCS = Interferential Current Stimulation)
IFCS Mode: Interferential Current Stimulation: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.

ETD500 TENS and IFCS Combination Device
TENS Mode:Transcutaneous Electrical Nerve Stimulation for Pain Relief: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.
IFCS Mode: Interferential Current Simulation: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.

ETD600 NMES and IFCS Combination Device
NMES Mode: Neuromuscular Electrical Stimulation: Relaxation of muscle spasm, increasing local blood circulation, maintaining and increasing range of motion, preventing or retarding muscle disuse atrophy, muscle reeducation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
IFCS Mode: Interferential Current Simulation: Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.

ETD700 TENS and NMES and IFCS Combination Device
TENS Mode: Transcutaneous Electrical Nerve Stimulation for Pain Relief. Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.
NMES Mode: Neuromuscular Electrical Stimulation. Relaxation of muscle spasm, increasing local blood circulation, maintaining and increasing range of motion, preventing or retarding muscle disuse atrophy, muscle reeducation, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
IFCS Mode: Interferential Current Simulation. Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post-surgical and post-traumatic pain.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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