December 23, 2020

Delta International Services & Logistics S.r.l
Mariella Giorgieri, CEO
Piazza Adriana 4
Rome, 00193
Italy

Re: K201458
Trade/Device Name: Scrambler Therapy Technology (Model ST-5A)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: November 23, 2020
Received: November 23, 2020

Dear Mariella Giorgieri:

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,

Robert Kang, PharmD
Acting 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

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)*
K201458

Device Name
Scrambler Therapy® Technology (Model ST-5A)

Indications for Use *(Describe)*
General Indications for Use :

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain.
- Symptomatic relief of acute pain.
- Symptomatic relief of post-operative 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary

5.0.1 Submitter/510(K) Holder

Company Name: Delta International Services & Logistics s.r.l.
Company Address: Piazza Adriana 4, Rome, Italy, 00193
Company Phone: +39 392 160 3399
Company e-mail: ceo@st-team.eu

Contact person:
Ms. Mariella Giorgieri, CEO
Delta International Services & Logistics S.r.l

Date the summary was prepared: June 22, 2020 (K201458)

Name of the device: Scrambler Therapy® Technology ST-5A
Trade name: Scrambler Therapy® Technology
Proprietary name: Scrambler Therapy®
Common or usual name: Scrambler Therapy®
No prior submission

5.0.2 Predicate Device

Device Name: Scrambler Therapy® MC-5A Device
(Manufactured in Korea by GEOMC Co., LTD under DIS&L license)
Applicant: Delta International Services & Logistics S.r.l (DIS&L)
510(k) Number: # K142666

Device Identification:
Scrambler Therapy® Technology Model ST-5A
(Manufactured in Italy under DIS&L license)

The associated accessories include:
1 - Set of connection cables for standard ECG electrodes consisting of 5 cables with different identification color + 1 spare gray cable.
1 - Power cable
1 - Instruction manual

5.0.3 Device Characteristics:

Software:
Version 3.1 of the ST-5A proprietary software is the same of firmware versions running on predecessor medical devices build under license with the same technology. All program units and waveform data are stored directly in the microcontroller onboard memory.
biologics: N/A
drugs: N/A
any patient-contacting materials:
coatings: ABS
additives: N/A
single-use: N/A
sterile: N/A
sterilization method [specify] : N/A

5.0.4 Environment of Use:
Hospital, Healthcare Facility, Hospice

Federal law restricts this device to sale by or on the order of a physician

5.0.5 Brief Written Description of the Device:
The ST-5A is a patented non-invasive electro-analgesia device, with 5 channels that deliver low-intensity stimuli (max. 5 mA) generated by a completely automated treatment program.
Five artificial neurons create "packets" (strings) of information recognized as "non pain", the content of which is controlled by a proprietary algorithm. This various information of "no pain" produces an immediate analgesic effect, capable of completely eliminating pain in real time. Up to 5 pairs of independent electrodes can be placed on the patient's body based on the need of the treatment.
Two microprocessors ensure the correct operation of the device by automatically establishing the optimal parameters of effectiveness and safety, which cannot be modified by the operator. In order to perform the treatment correctly, the operator only needs to position the electrodes and adjust the stimulation levels correctly. The placement of the electrodes requires scrupulous observance of the method of identifying the areas of pain treatment. If the treatment is performed correctly, normally the pain is zeroed (or reduced very close to zero) in real time regardless of the initial intensity and the pathology that generated it.

In this technology the concept of similarity that only considers the parameters of frequency, pulse width and intensity (used in other devices) is not applicable because they do not generate and do not characterize the specific information of “no pain” of the Scrambler Therapy®. In this sense any modification of the emissions of the Scrambler Therapy® in the form and organization of the flows in time, is functionally equivalent to the modification of the chemical formula of a drug.

5.0.6 Mechanism of action
In the Scrambler Therapy®, the therapeutic approach is no longer to inhibit the transmission of pain, but to transform the information of pain into “non-pain” using the same pathways. In the Scrambler Therapy® model, information becomes the central point of control of the plasticity of the pain system, both in the genesis of chronicity (induced by endogenous information of pain repeated over time) and in its regression (induced by synthetic information of “no pain” repeated over time).
The result of this theoretical model applied in the Scrambler Therapy® medical device, is an immediate and complete analgesic effect in treatment, and the return to normal physiological response after one or more cycles of treatment.

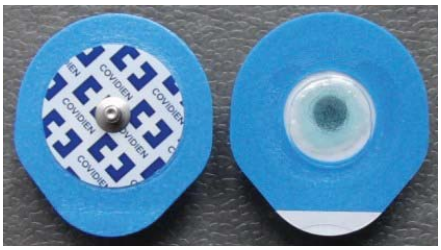
In view of these specific approach, it is quite clear that the concept of similarity that only considers the parameters of frequency, pulse width and intensity (used in other devices) for this Technology is not applicable because they do not generate and do not characterize the specific information of “no pain” of the Scrambler Therapy®. In this sense any modification of the emissions of the Scrambler Therapy in the form and organization of the flows in time (i.e. the specific strings of "no pain" information), is functionally equivalent to the modification of the chemical formula of a drug.

5.0.7 Any necessary feature to determine SE or device performance
The new device has the same technological characteristics that do not raise different questions of safety and effectiveness than the identified Delta International Services & Logistics Scrambler Therapy®

510(K) # K142666 predicate.

Energy source:
Power Supply 100-120V / 200-240V / 50-60 Hz
Materials of Use
External Chassis: ABS
Internal Chassis: Aluminum
Patient: Standard pre-gelled ECG Electrodes (single-use).

Type of electrode to use with Scrambler Therapy® Technology ST-5A: Kendall H34LG
FDA GUDID: https://accessgudid.nlm.nih.gov/devices/search?query=H34LG
DEVICE: Kendall (20884527005069)
Device Description: ECG Electrodes, H34LG, Foam, Wet Gel, Snap, Diagnostic, Stress



Basic Product Information
Shape / size Tear drop / 50 x 45 mm
Total product surface (incl. grip) 1730 mm2
Gel area 346 mm2
Adhesive area 1312 mm2

Materials Information
Backing material Polyethylene foam (PE), blue
Adhesive characteristics Medical grade pressure sensitive stress adhesive
Gel characteristics Wet gel
Supporting / back label Polyethylene terephthalate (PET) white
Release liner Polyethylene terephthalate (PET), one side siliconized
Sensor Polymer Ag/AgCl coated
Adapter / connector Stainless steel

Biocompatibility
Test acc. to DIN ISO 10993 passed
LATEX content no

Environment
Halogenated hydrocarbon content (e.g. PVC) no
Phthalate derivatives content (e.g. DEHP) no
RoHS directive in compliance

5.0.8 Key Performance Specifications/Characteristics of the Device

Intended Use
The ST-5A device has been designed for the pain therapy in hospital, outpatient facility and hospice by trained physicians or other trained healthcare personnel under physicians supervision.

Indications for Use

General
- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain.
- Symptomatic relief of acute pain.
- Symptomatic relief of post-operative pain.

5.1.0 Side-by-Side Comparison of Scrambler Therapy® Technology ST-5A Device with Predicate Device

Devices	Scrambler Therapy® Technology ST-5A Device	Scrambler Therapy® MC-5A Predicate Device
510(k) Number	K201458	K142666
Device Name, Model	Scrambler Therapy® Technology, ST-5A	Scrambler Therapy®, MC-5A
Manufacturer	Intellimed s.r.l.s. (Italy)	Geomc Co., Ltd. (Korea)
Power Source(s)	100-120V / 200-240V / 50-60 Hz	220 VAC
Number of Output Modes	one	one
Number of Output Channels	five	five
Method of Channel Isolation	transformer	transformer
Regulated Current or Regulated Voltage?	current	current

Software/Firmware/Microprocessor Control?	Yes (the same of the Predicate Device MC-5A)	Yes
Automatic Overload Trip?	Yes	Yes
Automatic No-Load Trip?	Yes	Yes
Automatic Shut Off?	Yes	Yes
Patient Override Control?	Yes	Yes
Indicator Display:		
- On/Off Status?	Yes	Yes
- Low Battery?	NA	NA
- Voltage/Current Level?	NA	NA
Timer Range (minutes)	20 to 60	20 to 60
Compliance with Voluntary Standards?	Yes	Yes
Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes	Yes
Maximum Output Voltage Available (+/- 2 %) (with software calibration correction)	2.2 V, load 500 ohm 4.4 V, load 1 KΩ	2.2 V, load 500 ohm 4.4 V, load 1 KΩ
Maximum Output Current (+/- 2 %)	Treatment mode: <=5 mA RMS (500 ohm – 10Kohm) Diagnostic mode (single wave without pauses): 5.5 mA	Treatment mode: <=5 mA RMS (500 ohm – 10Kohm) Diagnostic mode (single wave without pauses): 5.5 mA
Pulse Width	6.8 –10.9 mS	6.8 –10.9 mS
Frequency(Hz)	43-52	43-52
Stimulation Waveform	Biphasic pre-modulated mode of operation ▶ 011_APPENDIX 10-1 waveforms.pdf	Biphasic pre-modulated mode of operation (the same of the Device ST-5A ▶ 011_APPENDIX 10-1 waveforms.pdf
Maximum Current Density, (mA/cm²- with electrodes Gel area 3.46 cm2)	1.27 mA/cm²	1.27 mA/cm²
Maximum Power Density, (W/cm²- with electrodes Gel area 3.46 cm2)	0.00968W/cm²	0.00968W/cm²
Burst Mode a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	N/A for pre-modulated mode	N/A for pre-modulated mode
Intended use	• Symptomatic relief of chronic, intractable pain, post-surgical and posttraumatic acute pain • Symptomatic relief of acute pain	• Symptomatic relief of chronic, intractable pain, post-surgical and posttraumatic acute pain • Symptomatic relief of acute pain

	• Symptomatic relief of post-operative pain	Symptomatic relief of post-operative pain
Indications for use	**General** • Symptomatic relief of chronic, intractable pain, post-surgical and posttraumatic acute pain • Symptomatic relief of acute pain • Symptomatic relief of post-operative pain	**General** • Symptomatic relief of chronic, intractable pain, post-surgical and posttraumatic acute pain • Symptomatic relief of acute pain • Symptomatic relief of post-operative pain
Target population	• Patients with chronic pain. • Patients suffering from intractable pain, resistant to any other form of drug and non-drug therapy..	• Patients with chronic pain. • Patients suffering from intractable pain, resistant to any other form of drug and non-drug therapy..
Anatomical site	The whole body excluding: areas near the heart with trans-thoracic stimulation, in the upper part of the throat, in the head, in the mouth, and in parts affected by skin diseases or wounds	The whole body excluding: areas near the heart with trans-thoracic stimulation, in the upper part of the throat, in the head, in the mouth, and in parts affected by skin diseases or wounds
Where used	hospital, outpatient facility and hospice.	hospital, outpatient facility and hospice.
Human factors	Comply with IEC 62366-1	Comply with IEC 62366-1

Delta International Services & Logistics s.r.l. owns the commercial exploitation rights of the Scrambler Therapy® patents and TM technology, which are used in the construction of the device under our license, including the predicate device. For this reason the Delta International Services & Logistics s.r.l. Scrambler Therapy® ST-5A Device is identical in technological characteristics, usability, clinical performance to the Delta International Services & Logistics s.r.l. Scrambler Therapy® ST-5A Device.

5.1.1 Clinical Test

All the scientific literature referenced on Scrambler Therapy® is entirely applicable also to the Scrambler Therapy ® Technology ST-5A model, since there are no technological differences between the different generations of devices “MC-5A” that influence the efficacy and safety profile.

Note: *the proper use of Scrambler Therapy®, being operator-dependent, allows only for a partial double-blind or single-blind trial design. Attempts to do a complete double-blind clinical trial automatically cause substantial changes in the standard treatment protocol, which requires substantial patient interaction to determine proper placements of electrodes and intensity of treatment. These changes prevent the operator to follow the normal procedures registered in the healthcare authorizations and can erase or significantly reduce the efficacy of the treatment, consequently invalidating the scientific data.*

5.1.2 General use of a consensus standard

The Scrambler Therapy® Technology ST-5A Medical Device complies with the applicable requirements of the following international consensus standards:

- ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes

- EN ISO 14971: 2012, Medical devices — Application of risk management to medical, devices

- IEC 62304:2006+AMD1:2015 CSV, Medical device software life-cycle process

- EN ISO 15223-1: 2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements

- CEI EN 60601-1/A1:2014, Medical electrical equipment Part:1 General requirement for basic safety and essential performance

- EN 60601-1-2:2015 Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

- CEI EN 60601-1-6/A1:2016, Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- CEI EN 60601-2-10:2017, Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

- CEI EN 62366: 2016, Application of usability engineering to medical devices

The Scrambler Therapy® Technology ST-5A Medical Device is designed to be used only with lead wires which conform to FDA's Performance Standard for electrode lead wires, 21 CFR 898.

In conclusion, laboratory reports, the same type of user interface, the same patented technology, the same methods of use, indicate that the ST-5A device and the predicate device have no substantial differences that can influence the same expected performance of efficacy, security, usability.

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