DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2015

Delta international Service & Logistics S.r.l.
Ms. Mariella Giorgieri
CEO
Piazza Adriana 4
00193 Roma
Italy

Re: K142666
Trade/Device Name: Scrambler Therapy MC-5A Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: May 6, 2015
Received: May 11, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S
for Carlos Peña, PhD, MS
Director
Division and Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if you know): K142666

Device Name: SCRAMBLER THERAPY MC-5A DEVICE

Indication for Use:

The Scrambler Therapy MC-5A Device is indicated for:

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

Prescription Use ___ X _____ AND / OR Over-The-Counter Use ____ ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

1. SUBMITTER/510(K) HOLDER:

Company Name:	Delta International Services & Logistics S.r.l.
Company Address:	Piazza Adriana 4 00193, Roma - Italy
Company Phone:	039- 3921603399
Company Fax:	039-063215142
Company e-mail:	ceo@st-team.eu
Contact person:	Ms. Mariella Giorgieri CEO Delta International Services & Logistics S.r.l.
Date Summary Prepared:	May 13, 2015

2. DEVICE IDENTIFICATION

Common Usual Name:	Electrical Nerve Stimulator
Trade/Proprietary Name:	Scrambler Therapy MC-5A Device
Classification:	Class II
Product Code:	GZJ
Classification Panel:	882 Neurological Devices
Regulation Number:	882.5890

3. PREDICATED DEVICES

Predicate device	**510 (k) Holder**	**510 (k) No.**
SCRAMBLER MC-5A TENS DEVICE	COMPETITIVE TECHNOLOGIES, INC.	K081255

4. DEVICE DESCRIPTION

The Scrambler Therapy MC-5A Device is a multi-channel device which allows simultaneous treatment of a number of pain sites. Stimulation impulses are generated and controlled according to a stored program to provide pain relief.

5. INTENDED USE

The Scrambler Therapy MC-5A Device is indicated for:

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

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Delta International Services & Logistics s.r.l. claims substantial equivalence of the Scrambler Therapy MC-5A Device to the predicate devices based on the intended use, fundamental technology, and operation characteristics. A side-by-side comparison of the Scrambler Therapy MC-5A Device and the cited predicate device is included in the 510(k).

7. PERFORMANCE TESTING

Testing of the Scrambler Therapy MC-5A Device demonstrates that the device meets design and performance specifications.