December 31, 2020

Bios s.r.l.
Maurizio Bianchi
Head of QA/RA
Via Guido Rossa 10/12
Vimodrone, MI 20090
Italy

Re: K201239
Trade/Device Name: NuEra Tight Family, EMS Model
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 5, 2020
Received: October 8, 2020

Dear Maurizio Bianchi:

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,

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

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)*
K201239

Device Name
NuEra Tight Family, EMS Model

Indications for Use *(Describe)*
The NuEra Tight Family, EMS Model, is intended for:

- improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen;
- strengthening, toning and firming of buttocks, thighs and calves;
- improvement of muscle tone and firmness, for strengthening muscles in arms.

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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510(k) Summary

Contact Details

510(k) Number	K201239
510(k) Type	Traditional
Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20090 Vimodrone (MI) – Italy
Contact	Dr Eliana Russo
Date Prepared	24 June 2020
Device Name(s):	NuEra Tight Family, EMS Model
Model Refs	APMD151
Common Name	Powered Muscle Stimulator
Regulatory Class	Class II
Product Codes	NGX
Regulation Names	Stimulator, muscle, powered, for muscle conditioning

Predicate Device for EMS Treatments			
K190456	NGX, 890.5850	Powered Muscle Stimulator (BTL 799-2L)	BTL Industries, Inc.

Device Description

NuEra Tight Family, EMS Model, is a family of devices designed to:

- produce an electromagnetic field that induces electrical current in the muscles. By muscle stimulation, the system helps to strengthen, tone and firm the abdomen, buttocks, thighs and calves.

The device belonging to the NuEra Tight Family, EMS Model, generates an intense magnetic field which is used to stimulate muscles trough two EMS handpieces, one small and one large, which can treat body parts of different sizes.

Indications for Use

The NuEra Tight Family, EMS Model, is intended for:

- Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen;
- Strengthening, toning and firming of buttocks, thighs and calves;
- Improvement of muscle tone and firmness, for strengthening muscles in arms.

Predicate Device Comparison

The product specification, functionality, indications for use, and treatment parameters of the NuEra Tight Family, EMS Model, are the same or very similar to the legally marketed predicate and reference devices.

For the electromagnetic stimulation function, the subject device and predicate device have many identical, similar or substantially equivalent properties or features. No differences that could affect safety or effectiveness have been identified, as indicated in Table 1.

Table 1: Predicate device comparison table – NuEra Tight Family, EMS Model – Electromagnetic Stimulation

Feature	Subject device	Predicate device	Similarity
Device name	NuEra Tight Family (EMS Model)	BTL 799-2L	N/A
Device Manufacturer	Bios S.r.l.	BTL Industries, Inc.	N/A
510(K) Number	K201239	K190456	N/A
Product Code	NGX – Stimulator, Muscle, Powered	NGX – Stimulator, Muscle, Powered	Same
Regulation	21 CFR 890.5850	21 CFR 890.5850	Same
Indications for Use	The NuEra Tight Family (EMS Model) is intended: • for improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen; • for strengthening, toning and firming of buttocks, thighs and calves; • for improvement of muscle tone and firmness, for strengthening muscles in arms.	BTL 799-2L is indicated to be used for: • Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, toning and firming of buttocks, thighs and calves. • Improvement of muscle tone and firmness, for strengthening muscles in arms.	Same
Principle of action	Initiating action potential of nerves results in muscle contraction.	Initiating action potential of nerves results in muscle contraction.	Same
Clinical use	Prescription Use	Prescription Use	Same
Electrical Protection	Class I type BF	Class I type BF	Same
User Interface	Touch Screen	Touch Screen	Same
Firmware Controlled	Yes	Yes	Same
Type of energy	Magnetic Field	Magnetic Field	Same
Number of outputs	2	2	Same
Number of magnetic coils in the applicator	1	1	Same
Magnetic Field Intensity	Large HP: 0.5 – 1.8 T ± 20%	BTL 299-6 applicator: 0.5 – 1.8 T ± 20%	Same
	Small HP: 0.7 – 2.0 T ± 20%	BTL 299-7 applicator: 0.7 – 2.0 T ± 20%	Same
Pulse Repetition Rate	1-150 Hz	1-150 Hz	Same
Pulse Duration	Large HP: 280 ± 20% µs	BTL 299-6 applicator: 280 ± 20% µs	Same
	Small HP: 190 ± 20% µs	BTL 299-7 applicator: 190 ± 20% µs	Same
Therapy Time	Up to 60 min	Up to 60 min	Same

Table 2: Basic Unit Characteristics

This section is intended to describe basic unit characteristics. The parameters listed are assumed to be independent of the selected output mode. If this is not the case, or if the information is not applicable to the device, an explanation should be provided. If a specific parameter is not applicable (N/A), this should be noted.

Characteristics	**Bios Device**	**Predicate Device**	**Notes**
Device name	NuEra Tight Family (EMS Model)	BTL 799-2L	N/A
Device Manufacturer	Bios s.r.l.	BTL Industries, Inc.	N/A
510(K) Number	K201239	K190456	N/A
Power Source(s) - Method of Line Current Isolation Patient Leakage Current - Normal condition - Single fault condition	IEC 60601-1 compliant < 0,1 µA < 5 µA	IEC 60601-1 compliant < 0,1 µA < 5 µA	N/A
Average DC current through electrodes when device is on but no pulses are being applied (µA)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Number of Output Modes	1	1	N/A
Number of Output Channels - Synchronous or Alternating? - Method of Channel Isolation	2 Synchronous N/A	2 Synchronous N/A	No electrodes. Applicators are not connected to patient.
Regulated Current or Regulated Voltage?	Regulated voltage	Regulated Voltage	N/A
Software /Firmware /Microprocessor Control?	Yes	Yes	N/A
Automatic Overload Trip?	N/A	N/A	No electrodes. Applicators are not connected to patient.
Automatic No-Load Trip?	N/A	N/A	No electrodes. Applicators are not connected to patient.
Automatic Shut Off?	No	Not available	N/A
Patient Override Control?	Yes	Not available	N/A
Indicator Display: - On/Off Status? - Low Battery? - Voltage/Current Level?	Yes N/A No	Yes N/A No	N/A
Timer Range (minutes)	Up to 30 minutes	Up to 30 minutes	N/A

Compliance with Voluntary Standards? (If yes, specify) (If yes, specify)	N/A	N/A	N/A
Compliance with 21 CFR 898?	N/A	N/A	N/A
Weight	100 kg	Not available	N/A
Dimensions (in.) [W x H x D]	1350x560x710 mm (HxWxD) (53x22x28 in)	580×1380×580 mm (23×55×23 in)	N/A
Housing Materials and Construction	Steel and Injection Molded Plastics	Steel and Injection Molded Plastics	N/A

Table 3: Output Specifications			
An output mode is defined (for reporting purposes) as a version of a waveform produced by the unit. For example, biphasic symmetrical, biphasic asymmetrical, and monophasic would all be considered separate output modes. A copy of the following information should be completed for each output mode. If a specific parameter is not applicable (N/A), this should be noted.		Unique output mode. No electrical output delivered to the body for this EMS technology	
Characteristics	**Bios Device**	**Predicate Device**	**Notes**
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	N/A
Shape (e.g., rectangular, spike, rectified sinusoidal)	Sinusoidal	Sinusoidal	N/A
Maximum Output Voltage (specify units)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Maximum Output Current (specify units)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Pulse Width (specify units)	Large HP: 280 ± 20% µs	BTL 299-6 applicator: 280 ± 20% µs	N/A
	Small HP: 190 ± 20% µs	BTL 299-7 applicator: 190 ± 20% µs	N/A
Frequency (Hz)	1-150 Hz	1-150 Hz	N/A
For interferential modes only: - Beat Frequency (Hz)	N/A	N/A	N/A
For multiphasic waveforms only: - Symmetrical phases? - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Yes	Yes	N/A

Net Charge (mC per pulse)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Maximum Phase Charge, (mC)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Maximum Current Density (mA/cm²)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Maximum Average Current	N/A	N/A	No electrodes. Applicators are not connected to patient.
Maximum Power Density (W/cm²) (using smallest electrode conductive surface area)	N/A	N/A	No electrodes. Applicators are not connected to patient.
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	N/A	N/A	N/A
ON Time (seconds)	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A
Additional Features (if applicable)	N/A	N/A	N/A

Performance Data

Electrical safety and electro-magnetic compatibility

The NuEra Tight Family, EMS Model, has been tested and is in compliance with:

- IEC 60601-1; Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-1-2; Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests;
- IEC 60601-1-6; Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability;
- IEC 60601-2-10/A1; Medical Electrical Equipment - Part 2-10: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators;
- IEC 62304; Medical Device – Software Life Cycle Processes;
- ISO 14971; Medical Devices – Application Of Risk Management To Medical Devices

Software Verification and Validation

In addition to the electrical safety testing performed, software verification and validation was conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and validation was also performed on the NuEra Tight Family, EMS Model, in compliance with internal design control procedures. The results of this testing conclude the NuEra Tight Family, EMS Model, is determined to be safe and effective.

Functional Testing

Functional tests have been performed to confirm that the performance of the NuEra Tight Family, EMS Model, devices are aligned with the device technical specifications.

Biocompatibility

Based on the type and duration of body contact, existing biocompatibility data has been assessed in accordance with ISO 10993-1:2018 (FDA standards recognition # 2-258) and FDA guidance document *'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process": Guidance for Industry and Food and Drug Administration Staff*', 16 June 2016.
The NuEra Tight Family, EMS Model, has no contact with the skin of the treated patients.

Conclusion

Based upon the indications for use and known technical information provided in this pre-market notification, the NuEra Tight Family, EMS Model, devices has been shown to be substantially equivalent to currently marketed predicate and reference devices. Any differences are considered minor and do not raise new issues of the safety and effectiveness of the NuEra Tight Family, EMS Model, devices when compared to the predicate devices.