August 11, 2020

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

Re: K200359
Trade/Device Name: NuEra Tight RF Family
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: April 20, 2020
Received: April 20, 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K200359

Device Name
NUERA Tight RF Family

Indications for Use *(Describe)*
The NuEra Tight RF Family is intended for:

- to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
- to provide, with a massage device, a temporary reduction in the appearance of cellulite.

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	K200359
510(k) Type	Traditional
Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20090 Vimodrone (MI) – Italy
Contact	Eng. Maurizio Bianchi
Date Prepared	August 10th 2020
Device Name(s):	NuEra Tight RF Family
Model Refs	APMD145-1ch.US, APMD151-1ch.US
Common Name	Radiofrequency System
Regulatory Class	Class II
Product Codes	PBX
Regulation Names	Massager, vacuum, radio frequency induced heat

Predicate and Reference Devices

510(k) Ref	Pro Code/Reg No	Trade Name	Applicant
Predicate Device			
K151296	PBX, 878.4400	Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250)	Bios s.r.l.
Reference Device			
K133739	PBX, 878.4400	Electrosurgical cutting and coagulation device and accessories (TruSculpt)	Cutera

Device Description

NuEra Tight RF Family is a family of devices designed to:

- develop localized heat to warm the subcutaneous tissue by means of radio frequency energy, delivered through electrodes in contact with the patient.

Specifically, there are two devices in the family:

- NuEra Tight RF - radiofrequency generator with single RF electrode connector
- NuEra Tight RF Plus –radiofrequency generator with single RF electrode connector. The device has a different design, in particular for larger size, than the NuEra Tight RF, for the presence of a disabled electronic part that is the object of a different 510(k) submission. The detachable components to be used with the part not available are not provided with the Nuera Tight RF Plus.

The purpose of the treatment based on the radiofrequency system (NuEra Tight) is to raise the temperature inside the tissues up to maximum of 45°C. Therefore, depending on the treatment and intended use, different parts of the body can be treated.

The devices use RF electrodes of the capacitive (or monopolar) and resistive (or bipolar) types. Capacitive RF electrodes have different sizes and plug into an RF handpiece that provides connection to the RF generator (through the electrode connectors). Handpieces of different shapes are available to facilitate use by the operator on different body parts. Capacitive electrodes work in combination with a return plate that must be in contact with the patient's body during the treatment in order to close the circuit with the RF generator. Return plates can be reusable or disposable, with specific connectors on the panel below the front tray. One resistive electrode is provided fixed to a dedicated handpiece intended for the treatment of small body areas. The resistive electrode, being bipolar, is not meant to work with the return plate. One massage handpiece is provided to be used to add a mechanical treatment to the heat emission. All the handpieces are used with a small amount (approximately 1 mm layer) of cream, Parker Redux cream K782055 or similar. The cream purpose is to provide aid to transfer the heat.

A footswitch is provided as an optional user interface that allows to start and stop the medical treatment. It can be used as an alternative to the GUI start and stop button.

The pause handpiece can be used to pause the treatment without using the GUI.

Indications for Use

The NuEra Tight RF Family is intended:

- to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation;
- to provide, with a massage device, a temporary reduction in the appearance of cellulite.

Predicate Device Comparison

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

The technological similarities and differences between the NuEra Tight RF Family, model NuEra Tight, and the predicate and reference devices are described in comparison Tables 1 and 2.

Table 1: Predicate device comparison table – NuEra Tight RF Family - Radiofrequency

Feature	Subject device	Predicate device	Similarity
Device name	NuEra Tight RF Family	Biorevital RF MED/ThermiSmooth 250	N/A
Device Manufacturer	Bios s.r.l.	Bios s.r.l.	Same
510(K) Number	K200359	K151296	N/A
Product Code	PBX – Massager, Vacuum, Radio Frequency Induced Heat	PBX – Massager, Vacuum, Radio Frequency Induced Heat	Same
Regulation	21 CFR 878.4400	21 CFR 878.4400	Same

Table 1: Predicate device comparison table – NuEra Tight RF Family - Radiofrequency			
Feature	**Subject device**	**Predicate device**	**Similarity**
Indications for Use	The NuEra Tight RF Family is intended: • to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase local circulation; • to provide, with a massage device, a temporary reduction in the appearance of cellulite.	The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) device is intended to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. The Family of Radiofrequency System (Biorevital RF MED, ThermiSmooth 250) massage device is intended to provide a temporary reduction in the appearance of cellulite.	Same
Principle of action	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.	Electromagnetic waves penetrate in exposed tissue and produce heat, increasing the temperature on a certain part of the body for therapeutic purposes.	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	Radiofrequency waves	Radiofrequency waves	Same
Temperature Control	Yes	Yes	Same
Frequency	470 kHz; 1 MHz; 2 MHz; 4 MHz ; 6 MHz	470 kHz	Same for 470 KHz. For the other frequencies consider the reference device (Table 2)
Output RF Power	Max 250 W	Max 250 W	Same
Voltage	100 – 240 V	110 V or 220 V single phase	Same

Table 2: Reference device comparison table – NuEra Tight RF Family - Radiofrequency			
Feature	**Subject device**	**Reference device**	**Similarity**
Device name	NuEra Tight RF Family	TruSculpt RF Energy	N/A
Device Manufacturer	Bios s.r.l.	Cutera Inc	N/A
510(K) Number	K200359	K133739	N/A
Product Code	PBX – Massager, Vacuum, Radio Frequency Induced Heat	PBX – Massager, Vacuum, Radio Frequency Induced Heat	Same
Regulation	21 CFR 878.4400	21 CFR 878.4400	Same

Table 2: Reference device comparison table – NuEra Tight RF Family - Radiofrequency			
Feature	**Subject device**	**Reference device**	**Similarity**
Indications for Use	The NuEra Tight RF Family is intended: • to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as temporary relief of pain, muscle spasms, and increase local circulation; • to provide, with a massage device, a temporary reduction in the appearance of cellulite.	The TruSculpt RF energy is intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation. The TruSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite.	Same
Frequency	470 kHz; 1 MHz; 2 MHz; 4 MHz ; 6 MHz	300 KHz – 50 MHz	Similar

For the radiofrequency function, the only significant difference is that the predicate device K151296 works at a single frequency of 470 kHz, which is one of the frequencies available for the NuEra Tight. The reference device K133739 works at multiple frequencies in the range of 300 kHz – 50 MHz that includes the working frequencies of the devices in the NuEra Tight RF Family (470 kHz, 1 MHz, 2 MHz, 4 MHz and 6 MHz). This difference between the subject device and predicate device does not, therefore, raise any new types of safety or effectiveness questions.

Performance Data and Bench Test

Electrical safety and electro-magnetic compatibility

The NuEra Tight RF Family 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 60601-2-2; Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories;
- IEC 62304; Medical Device – Software Life Cycle Processes;
- ISO 14971; Medical Devices – Application Of Risk Management To Medical Devices

In addition, a test was performed and resulted demonstrated that the device can maintain the set skin temperature at 2 set point (minimum: 40°C and maximum: 42°C or 45°C depending on the electrode size) and it can maintain the skin temperature inside that interval of + 2°C for 15 minutes.

The test is executed for all electrodes in different parts of the patient (3 different body parts) and it is verified for all RF frequencies (470 kHz, 1 Mhz, 2 Mhz, 4 Mhz, 6 Mhz). In addition, the subset of tests is executed on different patients (2 additional patients) to demonstrate the independency of the results on a specific patient.

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 RF Family in compliance with internal design control procedures. The results of this testing conclude the NuEra RF Family is determined to be safe and effective.

Functional Testing

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

Biocompatibility

The NuEra Tight patient-contacting components have surfaces that, in accordance with the instructions for use, are categorized as ‘surface devices’, contacting ‘intact skin’, for a ‘limited’ time period (< 24 h), resulting in biocompatibility evaluation as follows, in accordance with Table A.1 of ISO 10993-1 and FDA guidance:

- Cytotoxicity: ISO 10993-5:2009, FDA standards recognition # 2-245
- Sensitization: ISO 10993-10:2010, FDA standards recognition # 2-174
- Intracutaneous reactivity: ISO 10993-10:2010, FDA standards recognition # 2-174

These patient-contacting components have all previously been cleared by FDA by means of successful 510(k) submissions. No further biocompatibility data is therefore included within this submission.

Conclusion

Based upon the indications for use and known technical information provided in this pre-market notification, the NuEra Tight RF Family 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 RF Family devices when compared to the predicate devices.