April 21, 2021

BIOS s.r.l.
Eliana Russo
Quality Assurance Manager
Via Guido Rossa 10/12
Vimodrone, MI 20090
Italy

Re: K210867
Trade/Device Name: NuEra Tight RF, NuEra Tight RF Plus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: March 19, 2021
Received: March 23, 2021

Dear Eliana Russo:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210867

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.

510 (k) Summary

Contact Details

510(k) Number	K210867
510(k) Type	Special
Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20055 Vimodrone (MI) – Italy
Contact	Dr Eliana Russo
Date Prepared	April 21th, 2021
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			
K200359	PBX, 878.4400	NuEra Tight RF Family	Bios s.r.l.

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 an additional electronic part that is cleared under K201239.

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.

The small area handpiece tip is provided sterile and disposable. The tip is Eto sterilized, the sterilization process was verified and validated using FDA-recognized standards UNI EN ISO 11138-1, UNI EN ISO 11138-2 and UNI EN ISO 11138-7. Also, the package integrity and shelf-life for this change have been evaluated through accelerated aging using American Society for Testing and Materials (ASTM) F1980.

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, that is Parker Redux cream K782055. 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 device.

The technological similarities and differences between the NuEra Tight RF Family, model NuEra Tight, and the predicate device are described in comparison Table 1.

Table 1: Predicate device comparison table – NuEra Tight RF Family - Radiofrequency			
Feature	**Subject device**	**Predicate device**	**Similarity**
Device name	NuEra Tight RF Family	NuEra Tight RF Family	Same
Device Manufacturer	Bios s.r.l.	Bios s.r.l.	Same
510(K) Number	K210867	K200359	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
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 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.	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; 1 MHz; 2 MHz; 4 MHz; 6 MHz	Same
Output RF Power	Max 250 W	Max 250 W	Same

Table 1: Predicate device comparison table – NuEra Tight RF Family - Radiofrequency			
Feature	**Subject device**	**Predicate device**	**Similarity**
Voltage	100 – 240 V	100 – 240 V	Same
Handpiece	Body, pen, small area composed of an handling part and the tip sterile and disposable	Body, pen, small area composed of an handling part and the tip reusable and provided non sterile and cleaned by the user	Same with the exception of the small area handpiece tip provided EtO sterile for single use

The difference is the introduction of a sterile and disposable configuration for the small area handpiece tip instead of the already cleared multiuse tip. The introduction of a sterile single use tip in place of the previous reusable tip to the cleared small area handpiece is to avoid to be carrier of bacteria and virus in sensitive and vulnerable areas of the body.

The indications for use and materials of construction remain unchanged from the cleared device, this difference does not, therefore, raise any new types of safety or effectiveness questions.

Performance Data and Bench Test

Functional Testing

Functional test has been performed to confirm that the performance of the NuEra Tight RF Family device, using the small area handpiece, is not impacted from the introduction of the sterilization process. Tips, after sterilization process, have been tested in order to demonstrate that the device can maintain the set skin temperature at 2 set point (minimum: 40°C and maximum: 42°C) and it can maintain the skin temperature inside that interval of + 2°C for 15 minutes.

The test is executed for all RF frequencies used with the small area handpiece (470 kHz, 1 Mhz, 2 Mhz, 4 MHz and 6 MHz).

Sterilization validation and shelf-life

Ethylene Oxide sterilization and Shelf-life validation activities for the new disposable configuration of the small area handpiece tip were conducted by external laboratories. Testing results demonstrate compliance with the following recognized FDA Standards:

ISO 11607, FDA standards recognition # 14-530

ISO 11135-1, FDA standards recognition # 14-529

ISO 10993-7, FDA standards recognition # 2-275

A summary of all the verification and validation activities performed on the NuEra Tight RF family are listed in Table 2 below.

Table 2 – Verification and validation activities on NuEra Tight RF family	
Test name	**Test Description**
Functional testing	The temperature stability in all operative status (multifrequency) and with all available electrodes provided with the devices was fully verified, validated and submitted under the NuEra Tight RF family submission K200359. The same protocol has been used to verify the performance of the small area handpiece tip, before and after the sterilization process.
Sterilization	Sterilization process validation of the small area handpiece tip was completed using an established method (EO). Package integrity testing and shelf-life validation has been performed. Testing results demonstrate compliance with ISO 11607, ISO 11135-1, and ISO 10993.

Conclusion

Based upon the indications for use, the known technical information and the performed tests listed above based on well-established methods and standards, the NuEra Tight RF Family device has been shown to be substantially equivalent to currently marketed predicate device. The only difference which is the introduction of the small area handpiece tip sterile and disposable in place of the previous not sterile and reusable one is 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 device.