May 2, 2023

BIOS s.r.l.
Martina Iturbe
RA Associate
Via Guido Rossa 10/12
Vimodrone, MI 20055
Italy

Re: K223907
Trade/Device Name: NuEra Tight RF Model APMD145.M70-US
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: December 28, 2022
Received: December 28, 2022

Dear Martina Iturbe:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.05.02 16:08:49 -04'00'

Mark Trumbore, 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)*

K223907

Device Name
NUERA Tight RF Model APMD145.M70-US

Indications for Use *(Describe)*
The NuEra Tight RF Model APMD145.M70-US 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	TBD
510(k) Type	Special
Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20055 Vimodrone (MI) – Italy
Contact	Dr Martina De Iturbe
Date Prepared	December 22, 2022
Device Name(s):	NuEra Tight RF Model APMD145.M70-US
Common Name	Massager, vacuum, radio frequency induced heat
Regulatory Class	Class II (21CFR§878.4400)
Product Codes	PBX
Regulation Names	Electrosurgical cutting and coagulation device and accessories

Predicate and Reference Devices

510(k) Ref	Pro Code/Reg No	Trade Name	Applicant
Predicate Device			
K210867	PBX, 878.4400	APMD145.M70 US	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. In addition, the NuEra Tight RF Plus has a larger size to accommodate an additional electronic part that has previously been cleared (K201239) and classified under procode NGX (Stimulator, Muscle, Powered, For Muscle Conditioning, 21 CFR § 890.5850); hence, this model provides the functions classified under both procodes PBX and NGX.

The treatment performed by the NuEra Tight RF Family consists of increasing the temperature of the treated tissues up to maximum of 45°C. Therefore, depending on the treatment and intended use, different parts of the body can be treated.

The models use RF monopolar and bipolar capacitive electrodes. Monopolar capacitive RF electrodes have different sizes and plug into an RF handpiece that provides connection to the RF generator. 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 are available as reusable or single use, with specific connectors on the panel below the front tray of the main control unit.

One bipolar capacitive electrode is provided fixed to a dedicated handpiece intended for the treatment of small body areas. Being bipolar, the electrode is not meant to work with a 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 a lubricious coating to allow the user to glide the electrode over the treated area and to ensure conduction with the return element on the bipolar electrode.

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.

A new accessory, proposed in this submission, is the Handsfree Accessory. The Handsfree will enable the same treatment without requiring the operator to manually move the handpiece and connected electrode over the entire treatment area. This is because the Handsfree electrodes (up to 8) can be connected together in a row with a belt, and also used with a double-sided adhesive tape, to better attach to the entire treatment area.

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 purpose of the Special 510(k) submission is to add the new model, APMD145.M70-US ("subject device"), to the NuEra Tight RF Family. The new model contains all the previously cleared features and functions of the predicate, predecessor model (K210867) and the additional Handsfree Accessory, as shown in Table 1 below.

Feature	**Predicate device:** NuEra Tight RF model (#APMD145-1ch.US)-(K210867)	**Subject device:** APMD145.M70-US
Device Manufacturer	Bios s.r.l.	Bios s.r.l.
510(K) Number	K210867	TBD
Product Code	PBX – Massager, Vacuum, Radio Frequency Induced Heat	PBX – Massager, Vacuum, Radio Frequency Induced Heat

Feature	**Predicate device:** NuEra Tight RF model (#APMD145-1ch.US)-(K210867)	**Subject device:** APMD145.M70-US
Regulation	21 CFR 878.4400	21 CFR 878.4400
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.
Principle of action	RF energy increases the temperature in the tissues for therapeutic purposes.	Identical to predicate
Clinical use	Prescription Use	Identical to predicate
User Interface	Touch Screen	Identical to predicate
Firmware Controlled	Yes	Similar to predicate
Type of energy	Radiofrequency waves	Identical to predicate
Max Temperature at Skin	45°C	Identical to predicate
Frequency	470 kHz; 1 MHz; 2 MHz; 4 MHz; 6 MHz	Identical to predicate
Accessories	Body handpiece	Identical to predicate
	Pen handpiece	
	Bipolar handpiece	
	Massage accessory	
	RF monopolar electrodes of sizes 20mm, 30mm, 40mm, Massage with 40 mm, 60mm, 80mm, 100mm	
	Disposable Return Plate	
	Reusable Return Plate	
	Foot Pedal	
	Small Area handpiece	

Feature	Predicate device: NuEra Tight RF model (#APMD145-1ch.US)-(K210867)	Subject device: APMD145.M70-US
	Pause Handpiece	
		Handsfree
Output RF Power	Max 250 W	Max 250 W
User-Supplied Items	Parker Cream	Parker Cream Double-sided Medical Adhesive Tape of 2-3 mm thickness

Performance Data and Bench Test

Verification and validation were performed on the Handsfree using methods established by the predecessor, predicate device. The tests were conducted in accordance with the following standards:

- EN 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 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 62304: Medical device software - Software life cycle processes
- ISO 14971: Medical devices - Application of risk management to medical devices

Conclusion

As designed, the subject device is essentially the predicate with the newly added Handsfree Accessory that provides another option for heating a larger area without requiring the user to continuously move the RF electrode. Testing confirms that the Handsfree operates in accordance with the same principles as the cleared electrodes in the predicate, which is to maintain the selected temperature at the treated site. The subject device therefore does not raise a different question of safety or effective and is substantially equivalent to its predecessor, predicate NuEra RF Tight model.