October 30, 2023

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

Re: K230755
Trade/Device Name: NuEra Tight RF Model OptiStream
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: August 3, 2023
Received: August 4, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2023.10.30 11:48:24 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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)*

Device Name
NUERA Tight RF Model OptiStream

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

- to provide topical heating to treat selected medical conditions such as for temporary relief of pain or muscle spasms and to increase local circulation on body and face.

- 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.

006_510 (k) Summary

Contact Details

510(k) Number	K230755
510(k) Type	Traditional
Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20055 Vimodrone (MI) – Italy
Contact	Dr. Martina De Iturbe
Date Prepared	August 2, 2023
Device Name(s):	NuEra Tight RF Model OptiStream
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	NuEra Tight RF Model 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 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.

The labeling changes proposed in this submission are to clarify that the use of the device to provide topical heating to increase local circulation is not limited to the body but can also include the face with the exception being within the orbital rim and on the neck.

Indications for Use

The NuEra Tight RF Family is intended:

- to provide topical heating to treat selected medical conditions such as for temporary relief of pain or muscle spasms and to increase local circulation on body and face.
- to provide, with a massage device, a temporary reduction in the appearance of cellulite.

Predicate Device Comparison

The purpose of the 510(k) submission is to update the indication statement with regards to the use of the device for the face and the related labeling statements regarding use on the face. The subject device, OptiStream, in Full Configuration, contains all the previously cleared features and functions of the predicate, predecessor model (K210867) and the additional 10 mm electrode, as shown in the table below. In its Basic Configuration, the OptiStream is provided with only the 10 mm and 20 mm electrodes.

Feature	Predicate device: NuEra Tight RF model (#APMD145-1ch.US)-	Reference device: Surgitron RF Generator with Pellevé Handpiece	Subject device: NuEra Tight RF Model OptiStream
Device Manufacturer	Bios s.r.l.	Cynosure, Inc. (formerly, Ellman International, Inc.)	Bios s.r.l.
510(K) Number	K210867	K132665	TBD
Product Code	PBX – Massager, Vacuum, Radio Frequency Induced Heat	GEI - Electrosurgical, Cutting & Coagulation & Accessories	PBX – Massager, Vacuum, Radio Frequency Induced Heat
Regulation	21 CFR 878.4400	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 Pellevé Non-Ablative Wrinkle Treatment System is indicated for the non-ablative treatment of mild to moderate facial wrinkles and rhytids.	The NuEra Tight RF Family is intended: • to provide topical heating to treat selected medical conditions such as for temporary relief of pain or muscle spasms and to increase local circulation on body and face. • 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.	RF energy increases the temperature in the tissues for therapeutic purposes.	Identical to predicate
Clinical use	Prescription Use	Prescription Use	Identical to predicate
User Interface	Touch Screen	Touch Screen	Identical to predicate
Firmware Controlled	Yes	Yes	Similar to predicate
Type of energy	Radiofrequency waves	Radiofrequency waves	Identical to predicate
Max Temperature at Skin	45°C	45°C for face	45°C (42°C for face)
Frequency	470 kHz; 1 MHz; 2 MHz; 4 MHz; 6 MHz	4 MHz	Identical to predicate
Accessories	Body handpiece Pen handpiece Bipolar handpiece		The Full Configuration includes the identical accessories as the

Feature	Predicate device: NuEra Tight RF model (#APMD145-1ch.US)-	Reference device: Surgitron RF Generator with Pellevé Handpiece	Subject device: NuEra Tight RF Model OptiStream
	Massage accessory		predicate, and a RF monopolar electrode of size 10 mm. Basic Configuration comes with the 10 mm and 20 mm electrodes.
	RF monopolar electrodes of sizes 20mm, 30mm, 40mm, Massage with 40 mm, 60mm, 80mm, 100mm	RF monopolar electrodes of sizes 7.5mm, 10mm, 15mm, 20mm	
	Disposable Return Plate		
	Foot Pedal		
	Small Area handpiece		
	Pause Handpiece		
User-Supplied Items	Parker Cream	Parker	Parker Cream

Performance Data and Bench Test

To support the proposed labeling changes, data reported in the literature and from bench and clinical testing of the subject device on the face were provided. Further, testing conducted on the 10 mm electrodes, using the methods and criteria that were established for the predicate electrodes, also showed that the 10 mm electrode performed as intended.

Conclusion

As designed, the subject device is essentially the predecessor predicate with the additional 10 mm electrode for heating small areas. The proposed addition to the indication statements to clarify the use of the subject device for heating the face does not pose a different safety or effectiveness question given that the FDA has cleared devices for heating the face to the same temperature as the subject device. Further, testing of the subject device on the face demonstrates that the subject device is able to induce and maintain such a temperature on the face. Hence, there is not a different safety or effectiveness question for the clarification that the subject device can also be used “on body and face” for topical heating to increase local circulation, or for the related labeling changes clarifying the use on the face. The subject device therefore is substantially equivalent to its predecessor predicate NuEra RF Tight model.