August 11, 2023

BIOS s.r.l.
Manuela Brambilla
Regional Regulatory Affairs Leader
Via Guido Rossa 10/12
Vimodrone, MI 20055
Italy

Re: K223856
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, GEI
Dated: July 14, 2023
Received: July 14, 2023

Dear Manuela Brambilla:

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: 2023.08.11 11:59:57 -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)*

K223856

Device Name
NuEra Tight RF and NuEra Tight RF Plus

Indications for Use *(Describe)*
The NuEra Tight RF and NuEra Tight RF Plus are 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.

- to provide, via heat-induced lipolysis at 1 and 2 MHz, abdominal circumference reduction with adjunctive improvement in the appearance of skin laxity.

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

510(k) Number	K223856
510(k) Type	Traditional
Applicant Information	Bios s.r.l. Via Guido Rossa, 10/12 20055 Vimodrone (MI) – Italy
Contact	Eng. Manuela Brambilla Phone: 0039-02-27304275 Email: regulatory@biosgroup.eu
Date Prepared	August 10, 2023
Device Name	NuEra Tight RF and NuEra Tight RF Plus
Common Name	Electrosurgical cutting and coagulation device and accessories
Regulatory Class	Class II (21CFR§878.4400)
Product Codes	GEI, PBX
Regulation Name	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 and NuEra Tight RF Plus	Bios s.r.l.
Reference Device			
K162512	GEI, PBX, 878.4400	truSculpt	Cutera, Inc.
K163415	GEI, 878.4400	SlimShape	Syneron Medical Ltd.

Device Description

NuEra Tight RF and NuEra Tight RF Plus are 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,

- 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 models 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 intended to be used with a small amount (approximately 1 mm layer) of an RF conductive cream (Parker Redux cream, cleared under K782055, or similar cream available in the US). The purpose of the cream 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 is an optional accessory can be used to pause the treatment without using the GUI.

Indications for Use

The NuEra Tight RF and NuEra Tight RF Plus are 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.
- to provide, via heat-induced lipolysis at 1 and 2 MHz, abdominal circumference reduction with adjunctive improvement in the appearance of skin laxity.

Predicate Device Comparison

The purpose of the 510(k) submission is to add the abdominal circumference reduction indications for the NuEra Tight RF models that were last cleared under K210867. The subject, predicate and reference devices, as shown in Table 1 below, all share the same operating principle, which is the delivery of RF energy by skin-contact electrodes to heat the underlying tissues to a certain temperature for a time period to achieve the intended effect. The reference devices are cleared with a circumference reduction indication.

TABLE 1. PREDICATE COMPARISON

Feature	Subject Devices	Predicate Devices	Reference Device #1	Reference Device #2
Device name	**NuEra Tight RF and NuEra Tight RF Plus**	**NuEra Tight RF and NuEra Tight RF Plus**	**truSculpt**	**SlimShape**
Device Manufacturer	Bios s.r.l., Italy	Bios s.r.l., Italy	Cutera, USA	Syneron Medical Ltd., Israel
510(k)	K223856	K210867	K162512	K163415
FDA Product Code	GEI, PBX	PBX	GEI, PBX	GEI
FDA Regulation Name	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories
FDA Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Operating Principle	Identical to Predicate	Radio frequency energy delivered to the tissue to induce heat and increase the temperature of the treated area for therapeutic purposes	Radio frequency energy delivered to the tissue to induce heat and increase the temperature of the treated area for therapeutic purposes.	Radio frequency energy delivered to the tissue to induce heat and increase the temperature of the treated area and concomitant vacuum suction of the treated area.
Indications for use	The NuEra Tight RF and NuEra Tight RF Plus are intended:	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.	- 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.	-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 and muscle spasms and increase in local circulation. - truSculpt massage device is intended to provide a temporary reduction in the appearance of cellulite	Does not have these indications.

TABLE 1. PREDICATE COMPARISON				
Feature	**Subject Devices**	**Predicate Devices**	**Reference Device #1**	**Reference Device #2**
Device name	**NuEra Tight RF and NuEra Tight RF Plus**	**NuEra Tight RF and NuEra Tight RF Plus**	**truSculpt**	**SlimShape**
	- to provide, via heat-induced lipolysis at 1 and 2 MHz, abdominal circumference reduction with adjunctive improvement in the appearance of skin laxity.	Do not have this proposed indication.	-2 MHz setting for the 40 cm^2 handpiece is indicated for temporary reduction in circumference of the abdomen.	The SlimShape System is indicated for non-invasive lipolysis (breakdown of fat) of the abdomen. The device is indicated for reduction in circumference of the abdomen.
RF Frequencies	470 kHz; 1 MHz; 2 MHz; 4MHz; 6 MHz. For the proposed additional abdominal circumference reduction indication: 1 and 2 MHz	470 kHz; 1 MHz; 2 MHz; 4MHz; 6 MHz	2 MHz	1 MHz
RF output power	Max 250 W	Max 250 W	Max 300 W	Not Provided in 510(k) Summary
Temperature Monitoring	Yes	Yes	Yes	Yes
Electrodes	Capacitive electrodes of 20, 30, 40, 40+massage, 60, 70, 80, and 100 mm in diameter.	Capacitive electrodes of 20, 30, 40, 40+massage, 60, 70, 80, and 100 mm in diameter	Capacitive electrode of 40 cm^2 area	Not described
How Used	Electrode is manually and continuously moved over the treated area by the operator to maintain the specified temperature of the treated tissue over the specified duration.	Electrode is manually and continuously moved over the treated area by the operator to maintain the specified temperature of the treated tissue over the specified duration.	Electrode is manually and continuously moved over the treated area by the operator to maintain the specified temperature of the treated tissue over the specified duration.	SlimShape is described as follows, "the SlimShape Applicator Belt incorporates an array of vacuum cavities; each cavity includes a pair of RF electrodes and a suction pad."
Prescription use	Rx only	Rx only	Rx only	Rx only
Clinical data to support the abdominal circumference reduction indication	NCT04406935	Not applicable	NCT02873104	NCT02999763

Performance Bench Testing

Bench testing to the following standards were repeated to confirm that the devices continue to meet their specifications:

- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012; A2:2021Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- EN 60601-1-2:2015 Medical electrical equipment General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests

No performance bench testing of the NuEra Tight RF models was conducted specifically for the additional circumference reduction indications because no device changes were needed to support this additional indication.

Performance Clinical Testing

A clinical study was performed to demonstrate the safety and effectiveness of the NuEra Tight RF Models for the proposed additional circumference reduction indications.

The study endpoints were as follows:

Primary Effectiveness Endpoint: Change in mean circumferential measurement at 12 weeks post last treatment compared to baseline within each treatment group.

Secondary Effectiveness Endpoints:

- Change in skin laxity compared to baseline at 4 and 12 weeks post last treatment.
- Aesthetic improvement compared to baseline at 4 and 12 weeks post last treatment.

Safety Endpoints:

- Subject Discomfort and Pain Levels during Treatment.
- Incidence and severity of device related adverse events during the study period.

The study was a multi-arm, prospective, randomized, and multi-center. Initially, three arms were included in the study design:

- Arm 1: NuEra treatment using 470 kHz
- Arm 2: NuEra treatment using 1 MHz
- Arm 3: NuEra treatment using 2 MHz

An equal 1:1:1 randomization allocation was planned. However, due to the COVID-19 pandemic that led to restrictions on non-essential medical procedures, quarantine, or reticence by subjects, the study experienced a high drop-rate. To maintain study power due to the availability of subjects during the COVID-19 pandemic and resource constraints, the sponsor revised the protocol to stop enrolling Arm 1. The second phase of the study randomized the remaining participants into only two arms: 1 MHz treatment or 2 MHz treatment, with a similar 1:1 randomized equal allocation. As each arm will be analyzed separately, the statistical power for each arm was unaffected.

The treatment regimen in the revised protocol remained the same as in the original protocol. Each subject received 4 treatments at 1 week intervals. Follow-up evaluations took place at 4 weeks (Follow-up 1) and 12 weeks (Follow-up 2) after the last treatment.

The results of the study were as follows:

For the 82 enrolled and randomized subjects:

- mean age of 46.8±11.3 years, with a range of 21.7-65.4 years;
- seventy-two (72) females and 10 males;
- self-identified to be: White (79%); Other (10%); Black or African American (6%); or Asian (5%), and to be of Hispanic or Latino ethnicity (13%); and,
- mean circumference of 85.93±8.51 cm, with a range of 67.93-104.6 cm.

Due to the COVID-19 pandemic, 18 subjects did not complete at least 3 of 4 treatment sessions. Also, 32 subjects had a major protocol deviation, through either not having the second follow-up visit (13 subjects) or had the second follow-up visit more than 4 weeks late (19 subjects).

The data supporting the additional indications are from subjects who completed at least 3 of the 4 treatment sessions. They include:

Primary Effectiveness Endpoint: The mean change (reduction) from baseline in waist circumference at 12 weeks follow up was found to be statistically significant in the 1 MHz (n=23) and 2 MHz (n=18) groups:

Secondary Effectiveness Endpoints:

- *Skin laxity:* Blinded assessors evaluated before/after pictures and identified improvement in skin laxity in a majority of subjects at the 4 and 12 week follow up visits*Aesthetic appearance:* Investigators and subjects were asked to assess aesthetic appearance after each visit (GAIS score). The majority in each group reported improvement in appearance.

In addition, blinded reviewers were asked to identify which photos of subjects (per visit and treatment arm in subjects who completed the study course and appeared for all follow-up visits) were 'before treatment' and 'after treatment' pictures. The results were that most pictures were correctly identified by the blinded reviewers. *Safety:*

- The median VAS Score was 0, with 50% of the subjects reported no pain or discomfort during any of the treatments and the average pain for all treatment arms was 1.6 (low-level of pain).
- One subject from the 2 MHz arm had a mild burn that was deemed related to the procedure, the adverse event (AE) resolved with no action taken (1/276 treatments, 0.3%).
- There were 2 AEs considered by the investigators as possibly related to the device or the procedure (diarrhea and back pain). The events were mild and resolved with no action.
- None of the AEs was considered serious.

Conclusion

The proposed additional indication for the subject devices has already been cleared for the reference devices at treatment frequencies of 1 MHz and 2 MHz and using the same RF induction technology as the subject devices, which show that the proposed additional indication does not present a new intended use for RF induction devices. The provided clinical data for the subject devices, operating at 1 MHz and 2 MHz frequencies, demonstrate that they are safe and effective for the proposed additional abdominal circumference reduction indication. The subject devices have the identical intended use and technological characteristics as their predicates, and the proposed additional indication does not create a new intended use or raise a new safety or effectiveness question. Thus, the subject devices are substantially equivalent to the predicate devices.