May 12, 2025

Novasonix Technology S.L
% Shilpa Gampa
Senior Manager
Freyr Inc
150 College Rd W #102
Princeton, New Jersey 08540

Re: K241733
Trade/Device Name: Hebe (np0000763)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: March 13, 2025
Received: March 13, 2025

Dear Shilpa Gampa:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated **April 16, 2025**. Specifically, FDA is updating this SE Letter **to correct a typo in the device name** as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Long Chen, Ph.D., OHT4: Office of Surgical and Infection Control Devices, **301-796-6389, long.chen@fda.hhs.gov**.

Sincerely,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.05.12 14:04:32 -04'00'

For
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

April 16, 2025

Novasonix Technology S.L
% Shilpa Gampa
Senior Manager
Freyr Inc
150 College Rd W #102
Princeton, New Jersey 08540

Re: K241733
Trade/Device Name: Hebe (np0000763); Hera (np0000706)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: PBX, GEX
Dated: March 13, 2025
Received: March 13, 2025

Dear Shilpa Gampa:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.04.16 07:26:47 -04'00'

For
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241733

Device Name
HEBE

Indications for Use *(Describe)*
HEBE is intended to provide topical heating to elevate tissue temperature for the treatment of selected medical conditions, including pain relief, muscle spasm reduction, and increased local circulation

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary

Contact Details

510(k) Number	K241733
510(k) Type	Traditional
Applicant Information	NOVASONIX TECHNOLOGY S.L c/ Pla de Ramasar 52, Pol. Ind, Carrer Pla del Ramassar Granollers, Barcelona, 08402, Spain
Contact	Mr. Carlos Navarro +34 931 356 541 cnavarro@novasonix.es
Data Prepared	13-March-2025
Device Name(s)	HEBE
Common Name	Massager, Vacuum, Radio Frequency Induced Heat
Regulatory Class	Class II (21CFR 878.4400)
Product Code	PBX
Regulation Names	Electrosurgical cutting and coagulation device and accessories

Predicate and Reference Devices

510(k) Ref	Pro Code/Reg No	Trade Name	Applicant
Primary Predicate Device			
K210867	PBX - Massager, Vacuum, Radio Frequency Induced Heat	NuEra Tight RF Family	Bios s.r.l.
Reference Device			
K161458	PBX -Massager, Vacuum, Radio Frequency Induced Heat	Deep Care	Indiba USA Inc.

Device Description

HEBE is a device indicated for radiofrequency (RF) treatments at 448kHz. This frequency is associated with pain reduction and improved functionality in patients with musculoskeletal disorders. This wavelength promotes ion mobilization between the intracellular and extracellular matrix and restores cell membrane permeability. The energy generated at 448 kHz improves cell membrane permeability, enhancing intracellular and extracellular exchange and tissue regeneration. Furthermore, high-intensity radiofrequency treatment at 448 kHz can induce significant hyperthermia, which can lead to a considerable increase in cell metabolism and accelerated recovery. These hyperthermal adaptations to radiofrequency treatment are based on vasodilatation, causing a targeted local increase of blood perfusion and decreases in muscle tension and spasm, increased oxygen and nutrient supply, and healing acceleration.

RF treatment can be applied through either capacitive or resistive electrodes that pass radiofrequency to the human body.

HEBE has 3 different technologies:

- Monopolar Capacitive Radiofrequency
- Monopolar Resistive Radiofrequency
- Bipolar Resistive Radiofrequency

Indications of Use

HEBE is intended to provide topical heating to elevate tissue temperature for the treatment of selected medical conditions, including pain relief, muscle spasm reduction, and increased local circulation.

Predicate Device Comparison

SrNo	Feature	Subject Device	Predicate Device	Reference Device	Similarity
1	Device Name	HEBE	NuEra Tight RF Family	Deep Care	N/A
2	Device Manufacturer	Novasonix Technology S.L.	Bios s.r.l.	Indiba USA Inc.	N/A
3	510(K) Number		K210867	K161458	N/A
4	Product Code	PBX - Massager, Vacuum, Radio Frequency Induced Heat	PBX - Massager, Vacuum, Radio Frequency Induced Heat	PBX -Massager, Vacuum, Radio Frequency Induced Heat	Same
5	Regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same

6	Indications for Use	HEBE medical device is intended to provide topical heating to elevate tissue temperature for the treatment of selected medical conditions, including pain relief, muscle spasm reduction, and increased local circulation.	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 Indiba Diathermia Radiofrequency Devices are intended to provide topical heating for the purpose of elevating tissues temperature for treatment of selected medical conditions such as relief of pain, muscle spasms, increase in local Circulation. The Massage device provided is intended to provide a temporary reduction in the appearance of cellulite.	Same

7	Principle of action	Radio frequency 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.	The RF energy generates a heating profile that produces a moderate temperature rise in the subcutaneous tissue. The temperature on the skin is measured using a separate IR (Infra-red) thermometer and there is an integrated massage device that can be used to massage the skin during cellulite treatment.	Same
8	Clinical use	Prescription Use	Prescription Use	Prescription Use	Same
9	Electrical Protection	Class I Type BF	Class I type BF	Class I type BF	Same
10	User Interface	Touch Screen	Touch Screen	Touch Screen	Same
11	Firmware Controlled	Yes	Yes	Yes	Same
12	Type of energy	Radiofrequency waves	Radiofrequency waves	Radiofrequency waves	Same
13	Temperature Control	Yes with external IR thermometer	Yes	Yes with external IR thermometer	Same
14	Applicator Types	Reusable Electrodes: Monopolar Capacitive (Coating material: Polyamide) Monopolar Resistive (Material: Stainless steel)	Reusable Electrodes: Monopolar Capacitive Bipolar Resistive Small handpiece tip provided sterile and disposable	Reusable Electrodes: Monopolar Capacitive (Coating material: Polyamide) Monopolar Resistive (Material: Stainless steel)	Same with K161458. With the exception that the predicate device has no

		Bipolar Resistive (Material: Stainless steel) The electrodes are inserted into a handle/handpiece Electrodes dimensions and Power density: Capacitive: Size in diameter (Power density) There are four sizes 20 mm (63.69 W/cm²), 40mm (15.89 W/cm²), 60mm (28.26 W/cm²) and 80-mm (4.37 W/cm²), and 5.5 mm thickness. Resistive: Size in diameter (Power density) There are three sizes. 40mm (9.93 W/cm²), 60mm (4.42 W/cm²) 80mm (2.48 W/cm²) and 5.5 mm thickness. Bipolar: Size in diameter (Power density) There are two sizes. 30mm (48.82 W/cm²), 70mm (6.9 W/cm²), and 5.5 mm thickness).	The electrodes are inserted into a handle/handpiece. Electrodes Dimensions for Monopolar Capacitive: ø20 mm, ø30 mm, ø40 mm, ø60 mm, ø70 mm, ø80 mm, ø100 mm, ø40 mm	The electrodes are inserted into a handle/handpiece. Electrode dimensions Capacitive: Flat circular shape and sized at 30-, 40-, 55- and 65-mm diameter. Resistive: Flat circular shape and sized at 35-, 50- and 65-mm diameter.	bipolar applicator Same with K210867 with the exception of the small area handpiece tip provided EtO sterile for single use and does not use Monopolar resistive type of applicator. Applicator area for Bipolar electrode not reported. Power density not reported for K210867 & K161458

15	Use of Return Plate	Yes, except in treatments with bipolar electrode. Characteristics: Flexible Size: 20x14 cm; Area covered 280 cm^2 (small) Size 28x20 cm; Area covered 560 cm^2 (large). Material: Stainless Steel	Yes, except in treatments with bipolar electrode. Characteristics: Disposable return plates	Yes Characteristics: Flexible Size: 20x26 cm Area covered 520 cm^2 Material: Stainless Steel	Same except that area covered information is not available for K210867
16	Use of conductive cream	Yes, to provide thermal transfer assistance.	Yes, to provide thermal transfer assistance.	Yes, to provide thermal transfer assistance.	Same
17	Other Accessories	Handles, IR thermometer, power cable, trolley	Handles, IR thermometer, power cable, trolley	Handles, IR thermometer, power cable, trolley	Same
18	Biocompatibility	ISO 10993	ISO 10993	ISO 10993	Same
19	Type of body contact	Superficial contact on healthy skin	Superficial contact on healthy skin	Superficial contact on healthy skin	Same
20	Sterilization	No	Only the small area handpiece tip provided EtO sterile for single use.	No	Same

21	Electrode reprocessing	Yes, after electrode cleaning	Yes, except for the small area handpiece tip provided EtO sterile for single use.	Yes, after electrode cleaning	Same
22	Shelf life	50000 Hours in continuous operation	Information not available	Information not available	N/A
Performance specifications					
23	Treatment temperature range	+43 °C – +45 °C	+40 °C - +42 °C	+10 °C – +40 °C	Please refer to the foot notes [a] at the end of the table
24	Frequency	448 KHz	470 kHz; 1 MHz; 2 MHz; 4 MHz; 6 MHz	400 kHz - 449 kHz	Same
25	Output RF Power	Max 200 W	Max 250 W	Max 200 W	Same
26	Voltage	100-240 V	100 - 240 V	100 - 240 V	Same
Safety Features					

27	Temperature and Power	The device contains current sensor in the electronics that generates the RF signal. By controlling the current, the treatment temperature is controlled. If the measured current is out of the acceptance range the device stops and issues a warning through the GUI. -Internal over-temperature protection by means of a fan that is activated and regulates its power according to the measurement of an internal temperature sensor in the device. Controlling the current intensity generated by the electronics generating the RF also controls the output power.	Information not available	-Output protected against accidental short circuit between neutral plate and active electrode. -Output over-voltage limitation -Output over-power limitation -Contact detection with patient skin -Internal over-temperature protection	Same with Indiba internal over-temperature protection.

[a] The 510(k) Summary of the reference device K161458 stated in its performance testing "The validation confirmed that after a minimum of 5 minutes the Indiba Diathermia Radiofrequency Device can raise, and maintain, the skin temperature to the range of 40-45 °C under capacitive and resistive applications."

Performance Date and Bench Test

The Verification and validation were performed on the device using the established methods by using the predicate device.

The test was conducted in accordance with the following standards.

- 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: 2009 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

The Biocompatibility of the device was conducted in accordance with the following standards.

- ISO 10993-1-2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5-2009: Biological evaluation of medical devices - Part 5 Test for invitro cytotoxicity
- ISO 10993-10-2010: Biological evaluation of medical devices - Part 10 Test for irritation and Skin Sensitization

Conclusion

The HEBE has the same intended use and similar indications for use, technological characteristics and principles of operation as its predicate device & Reference device. The performance testing the non-clinical testing is performed and its similar to the Predicate device.

HEBE devices are safe and effective and are substantially equivalent to the predicate devices in terms of performance.