July 30, 2021

Neauvia North America
Joy Willard
Director of Quality, Regulatory and Clinical Affairs
8480 Honeycutt Road
Raleigh, North Carolina 27615

Re: K202780
Trade/Device Name: Sectum System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX, GEI
Dated: June 30, 2021
Received: July 1, 2021

Dear Joy Willard:

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)*
K202780

Device Name
Sectum

Indications for Use *(Describe)*
The Sectum control unit is a high frequency generator 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, increase in local circulation and provide a temporary reduction in the appearance of cellulite. The Sectum control unit utilizes a BODY and PRECISION applicator for delivering high frequency electrotherapy to tissue.

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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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Neauvia Sectum System

(a)(1). Submitted By:

Neauvia North America.
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Raleigh, NC 27615
United States of America

Contact Person: Joy Willard
Director of Quality, Regulatory and Clinical Affairs
Telephone – (984) 777-5296
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Date: June 29, 2021

(a)(2). Proprietary Name: Sectum System

Common Name(s): Electrosurgical generator, Radio Frequency Induced Heat

Classification Name: 21 CFR 878.4400 Electrosurgical Cutting and Coagulation and Accessories

Regulatory Class: II
Product Codes: PBX, GEI
Classification Panel: General & Plastic Surgery

(a)(3). Predicate Devices: K143554 – Venus Legacy CX
Venus Concept Ltd., Weston FL, USA

Reference Devices: K203144 – MicroPen Evo
K210129 – RF Thermal System

(a)(4). Device Description

The Sectum control unit is a radiofrequency energy generator employed for a variety of aesthetic applications. The control unit output is set and monitored via touchscreen and controlled by foot switch. The control unit can be used with corded bipolar Precision and Body applicators.

(a)(5). Indications for Use

The Sectum control unit is a high frequency generator intended to provide topical heating for the purpose of elevating tissue temperature for the treatment of selected medical conditions, such as reliefof pain and muscle spasms, increase in local circulation and provide a temporary reduction in the appearance of cellulite. The Sectum control unit utilizes a BODY and PRECISION applicator for deliveringhigh frequency electrotherapy to tissue.

(a)(6). Substantial Equivalence: - Technological Characteristics

The subject devices included in The Neauvia Sectum System are substantially equivalent to predicate device in performance, options, and size. The system emits RF current to heat body and face tissues.

The following table compares the Sectum device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Description	**Subject Device** **Neauvia Sectum Electrosurgical Generator with 2 applicators: BODY and PRECISION**	**Venus Legacy CX** **Venus Concept Ltd.** **(K143554)**
Class, Product Code, Regulation	Class II, PBX & GEI, 21 CFR 878.4400	Class II, GEI & PBX, 21 CFR 878.4400
Indications for Use	The Sectum control unit is a high frequency generator 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 and provide a temporary reduction in the appearance of cellulite. The Sectum control unit utilizes a BODY and PRECISION applicator for delivering high frequency electrotherapy to tissue.	The Venus Legacy CX device is intended for the treatment of the following medical conditions; using the LB2 and LF2 applicators for delivery of non-thermal RF combined with massage and magnetic field pulses: • Relief of minor muscles aches and pain, relief of muscle spasm • Temporary improvement of local blood circulation • Temporary reduction in the appearance cellulite
Method of Activation	Footswitch	Footswitch or finger switch
User Interface	Touchscreen on front of generator allows user to select mode and output	Touchscreen on front of generator allows user to select mode and output
Energy Delivered	RF Energy Massage	RF Energy Pulsed Magnetic Field (PMF) Vacuum
Modes Available	BIPOLAR	BIPOLAR
Max Power Output	BODY: 100W PRECISION: 100W	Up to 150W
Temperature Sensors	Applicators are equipped with treatment area temperature monitoring system	Applicators are equipped with treatment area temperature monitoring system
Output frequency	480 kHz for Bipolar Precision and Body applicators	Not Listed
Max Voltage Output	1 kV	Not Listed
Line Frequency	50/60 Hz	Not Listed

Control Unit Weight	5 kg	Not Listed
Control Unit Dimensions	410 x 325 x 155 mm	Not Listed
Applicator Dimensions, weight	Body: 145 x 140 x 100 mm, 345g Precision: 180 x 75 x 50 mm, 150g	Not Listed
Applicator: number of electrodes	Body: 6 Precision: 2	4D Body: 8
Standards Compliance	IEC60601-1 IEC60601-1-2 IEC60601-2-2 IEC60601-1-6 IEC60601-1-8	IEC60601-1 IEC60601-1-2 IEC60601-2-2

(b)(1). Substantial Equivalence: - Non-Clinical Evidence

Verification and validation activities were successfully completed and establish that the Sectum control unit performs as intended. Testing included the following:

Compliance with Electrical Safety and EMC standards:

IEC 60601-1:2005 (Third Edition) + A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests

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 60601-1-6:2010 + A1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

IEC 60601-1-8:2006 + A1:2012 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices. This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Skin surface temperature testing was completed proving the device is able to maintain tissue temperatures within the therapy specific limits.

Biocompatibility testing was evaluated on patient contacting materials per ISO 10993-1. Cytotoxicity and irritation testing show the components with patient contact are not cytotoxic per ISO 10993-5 or irritating per ISO 10993-10.

(b)(3). Substantial Equivalence – Conclusions

Neauvia Sectum device does not raise any new concerns of safety and efficacy compared to the predicate devices. The similar technological characteristics, indications for use and results of performance testing support the substantial equivalence of the Neauvia Sectum to the predicate device.