September 10, 2020

Cartessa Aesthetics
% Connie Hoy
Consultant
Hoy and Associates
3916 North Potsdam Ave
Souix Falls, South Dakota 57104

Re: K201738
Trade/Device Name: SubNovii Advanced Plasma Technology
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 21, 2020
Received: June 25, 2020

Dear Connie Hoy:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
510(K) 201738

Device Name

SubNovii Advanced Plasma Technology

Indications for Use *(Describe)*

The SubNovii is intended for the removal and destruction of skin lesions and coagulation of 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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"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."

This 510(K) Summary of safety and effectiveness for the SubNovii Advanced Plasma Technology is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cartessa Aesthetics
Address:	175 Broadhollow Rd Melville, NY 11747
Contact Person:	Gabe Lubin
Telephone:	877-662-2783 glubin@cartessaaesthetics.com
Preparation Date:	May 27, 2020
Device Trade Name:	SubNovii Advanced Plasma Technology
Common Name:	Electrosurgical, cutting & coagulation & accessories
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
Legally Marketed Predicate Devices:	Neauvia North America, Inc. Plasma IQ
510(K) number:	K192813
Regulatory Class:	Class II Prescription Use
Description of the SubNovii:	The SubNoviiI Advanced Plasma Technology is a handheld battery powered device that, when activated and placed in close proximity to the skin, generates an ionized electrical arc through the tip of an electrode (Tip) to the skin without the device or the electrode touching the skin. The SubNovii Advanced Plasma Technology consists of the SubNovii handpiece, single use disposable tips and a battery charger.
Intended use of SubNovii:	The SubNovii is used in the removal and destruction of skin lesions and the coagulation of tissue.
Performance Testing:	The following performance testing was conducted to prove compliance with performance requirements and support substantial equivalence:

Test	Objective	Results
Electrical	Compliance with EN 60601-1	Pass
	Compliance with EN 60601-1-2	Pass
Thermal Effects on 4 Yucatan mini Pig tissues (liver, kidney, muscle and skin) per FDA Guidance Premarket Notification (510(K)) Submission for Electrosurgical Devices for General Surgery	The tests were conducted on 4 Yucatan mini Pig tissues (liver, kidney, muscle and skin). Histological evaluation with nitro blue tetrazolium (NBT) demonstrated the tissue damages by the subject device are less than 0.25mm, which is considered superficial and substantially equivalent to the tissue damages by the predicate device.	Equivalent

Results of Clinical Study: A human clinical study was not required as the device is substantially equivalent to the predicate devices.

Technical Specifications / Indications for Use Comparison:

	510(K) Submission **SubNovii** **K201738**	**Predicate** **Neauvia, Inc.** **PLASMA IQ** **K192813**
Characteristic		
Indications for Use	Intended for the removal and destruction of skin lesions and coagulation of tissue.	Intended for the removal and destruction of skin lesions and coagulation of tissue.
Mode of Operation	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Plasma Radiofrequency energy ionizes the air creating a Plasma stream
Output	Monopolar	Monopolar
Power Supply	110-250 VAC 50/60 Hz	110-250 VAC 50/60 Hz

Frequency	40kHz	40kHz
Max Power Output	5W	5W
System Components	System consists of a handpiece that incorporates the electrosurgical generator unit, docking station, and an active electrode.	System consists of a handpiece that incorporates the electrosurgical generator unit, docking station, and an active electrode.
Electrical Safety Standards	Complies with IEC60601-1, IEC60601-1-2	Complies with IEC60601-1, IEC60601-1-2,

Conclusion: The Subnovii Advanced Plasma Technology device has the same technology, principle of operation, indications for Use, and technical specifications as the predicate device. Performance test results also demonstrated the subject device can perform the same intended use as safely and effectively as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.