



January 17, 2023

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

Re: K223222

Trade/Device Name: Plasma IQ
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 10, 2023
Received: January 11, 2023

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,


Colin K. Chen -S

for

Long Chen, Ph.D.
Acting 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

Indications for Use

510(k) Number (if known)

K223222

Device Name

Plasma IQ

Indications for Use (Describe)

Plasma IQ is used in 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

Date Prepared: October 17, 2022

Sponsor: Neauvia North America

Device Information

Device Name: Plasma IQ
Common Name: Electrosurgical, Cutting & Coagulation & Accessories
Class: II
Product Code: GEI
Regulation: 878.4400
Submission Type: Traditional 510k (Original Submission)

Predicate Information

Primary Predicate: K212329 – Plasma IQ
Reference Device: K201738 - Subnovii

Contact Information

Joy Willard
Director of Quality, Regulatory and Clinical Affairs
Phone: (984) 777-5296
Email: Joy@neauvia-us.com

1. Intended Use

PLASMA IQ is used in the removal and destruction of skin lesions and coagulation of tissue.

2. Device Description

PLASMA IQ utilizes a treatment method called plasma sublimation, which causes controlled skin damage through the generation of an electrical arc. The arc between the electrode tip and the skin is created by a radio frequency generator housed in an electrosurgical unit (handpiece) that ionizes the gas particles in the air. A straight active electrode made of 316L stainless steel is available with the system. The handheld device is cordless and is charged in a docking/charging station prior to use.

3. Performance Testing

No performance testing data was provided in this submission other than what was provided in the predicate (K212329) to establish substantial equivalence.

4. Substantial Equivalence to the Predicate Device

Trade Name	Submission Device	Predicate Device K212329
Manufacturer	Berger & Kraft Medical	Berger & Kraft Medical
510(k) #	Pending	K212329
Indications	Used in the removal and destruction of skin lesions and coagulation of tissue.	Used in the removal and destruction of skin lesions and coagulation of tissue.
Mode of Operation	Plasma	Plasma
Output	Monopolar	Monopolar
Power Supply	110 – 250 VAC 50/60 Hz	110 – 250 VAC 50/60 Hz
Frequency	40 kHz	40 kHz
Max Output Power	5 W	5 W
Output Impedance	54,000	54,000
System Components	System consists of a handpiece that incorporates the electrosurgical generator unit, Charging Station and two active electrode designs	System consists of a handpiece that incorporates the electrosurgical generator unit, Charging Station and two active electrode designs
Electrical Safety Standards	Complies with EN60601-1, EN60601-1-2, EN60601-2-2	Complies with EN60601-1, EN60601-1-2, EN60601-2-2

5. Substantial Equivalence to the Reference Device

Trade Name	Submission Device	SubNovii K201738

510K number	Pending	K201738
Mode of Operation	Plasma	Plasma
Output	Monopolar	Monopolar
Power Supply	110 – 250 VAC 50/60 Hz	110 – 250 VAC 50/60 Hz
Frequency	40 kHz	40 kHz
Max Output Power	5 W	5 W
Output Impedance	54,000	54,000
System Components	System consists of a handpiece that incorporates the electrosurgical generator unit, Charging Station and 2 Electrodes	System consists of a handpiece that incorporates the electrosurgical generator unit, Charging Station and 2 Electrodes
Electrical Safety Standards	Complies with EN60601-1, EN60601-1-2, EN60601-2-2	Complies with EN60601-1, EN60601-1-2, EN60601-2-2

6. Conclusion

The Plasma IQ that is subject to this submission is the same device that was cleared in K212329. No changes have been made to this device.

The Plasma IQ is substantially equivalent to the predicate device. The intent of this submission is to amend the labeling to remove a contraindication. There are no new questions regarding safety or effectiveness raised by the change in the labeling.