December 9, 2021

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

Re: K212329
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: October 18, 2021
Received: October 19, 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K212329

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.***

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510K Summary
Plasma IQ
K212329

Date Prepared: December 7, 2021

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: | K192813 – 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

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## 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 (K192813) to establish substantial equivalence.

## 4. Substantial Equivalence to the Predicate Device

| **Trade Name** | **Submission Device** | **Predicate Device K192813** |
|---|---|---|
| Manufacturer | Berger & Kraft Medical | Berger & Kraft Medical |
| 510(k) # | K212329 | K192813 |
| Indications | Used in the removal and destruction of skin lesions and coagulation of tissue. | Used in the removal and destruction of skin lesions andcoagulation of tissue. |
| Mode of Operation | Plasma | Plasma |
| Output | Monopolar | Monopolar |
| Power Supply | 110 – 250 VAC<br>50/60 Hz | 110 – 250 VAC<br>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 handpiecethat incorporates the electrosurgical generator unit, Charging Station and two active electrode designs |
| ElectricalSafety 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<br>K201738** |
|---|---|---|
| 510K number | K212329 | K201738 |
| Mode of Operation | Plasma | Plasma |
| Output | Monopolar | Monopolar |
| Power Supply | 110 – 250 VAC<br>50/60 Hz | 110 – 250 VAC<br>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 |
| ElectricalSafety 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 K192813. 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. This removal of the contradiction is supported by clincial evidence. There are no new questions regarding safety or effectiveness raised by the change in the labeling.