



March 6, 2020

Neauvia North America, Inc  
Misty Williams  
Executive VP Regulatory & Clinical Affairs  
8480 Honeycutt Rd  
Raleigh, North Carolina 27615

Re: K192813

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: February 3, 2020  
Received: February 4, 2020

Dear Misty Williams:

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K192813

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.

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## 510K Summary – Plasma IQ

As required by 807.92(c)

Date Prepared: March 5, 2020

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: K161134 – Bovie Derm 941, Electrosurgical Generator  
Bovie Medical Corporation, Clearwater, FL

### Contact Information

Misty Williams  
Executive Vice President of Regulatory and Clinical Affairs  
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Email: misty@neauvia-us.com

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## 1. Intended Use

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

## 2. Device Description

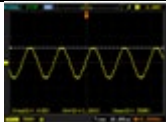
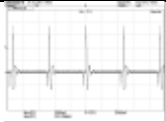
PLASMA IQ utilizes a treatment method called plasma sublimation, which causes controlled skin damage through the generation of an electrical arc. The arc between the electrode tip and the skin is created by a radio frequency generator housed in an electrosurgical unit (handpiece) that ionizes the gas 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

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
Tissue Testing	Compare thermal spread of devices	Equivalent
Packaging	Compliance with EN 22248	Pass

## 4. Substantial Equivalence

Trade Name	Submission Device	Predicate Device – Bovie DERM 941 Electro-surgical Generator
Manufacturer	Berger & Kraft	Bovie Medical Corporation
510(k) #	K192813	K161134
Indications	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	Radiofrequency
Output	Monopolar	Monopolar
Power Supply	110-250 VAC 50/60 Hz	100-240 VAC 50-60 Hz
Frequency	40 kHz	368 kHz
Max Output Power	5 W	40 W
Output Impedance	54,000 $\Omega$	200 $\Omega$
Waveform		
System Components	System consists of a handpiece that incorporates the electro-surgical generator unit, docking station, and an active electrode.	System consists of an electro-surgical generator unit, a handpiece, and dermal tips.
Electrical Safety Standards	Complies with IEC60601-1, IEC60601-1-2, IEC60601-2-2	Complies with IEC60601-1, IEC60601-2*, and EN60529

\*As listed in K170188 510(k) Summary

## 5. Conclusion

The predicate Bovie Derm 941 and the PLASMA IQ both produce RF energy to remove and destroy skin lesions and coagulate the tissue. The maximum output power of the Plasma IQ device is less than that of the Bovie Derm 941; however, the Plasma IQ and Bovie Derm 941 are substantially equivalent. There are no different questions of safety and effectiveness. Therefore, the subject device and predicate device are

substantially equivalent. Tissue testing, electrical testing (EMC testing) and packaging testing meet the current standards.