March 22. 2022

GMV S.r.l.
Andrea Cancelli
QA Manager
Via Roberto Parabeni 37
Rome 00173
Italy

Re: K210693
Trade/Device Name: PLEXR PLUS
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 19, 2022
Received: January 25, 2022

Dear Andrea Cancelli:

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)*
K210693

Device Name
PLEXR PLUS

Indications for Use *(Describe)*
Plexr Plus 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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510 (k) SUMMARY

SUBMITTER INFORMATION

A. Company Name: GMV S.r.l.

B. Company Address: Via Roberto Paribeni, 37
00173 Rome -Italy

C. Company Phone: +39-06 94315964
Company Fax: +39 06 98380555
Company e-mail: info@gruppogmv.it

D. Contact person: Andrea Cancelli
QA Manager
GMV S.r.l.

E. Date Summary Prepared: 2nd March 2021

DEVICE IDENTIFICATION

A. Device Name: PLEXR PLUS

B. Common Name: Electrosurgical, Cutting & Coagulation & Accessories

C. Classification: Class II

D. Product Code: GEI

E. Regulation Number: 878.4400

E. Submission Type: 510k (Original Submission)

LEGALLY MARKETED PREDICATE DEVICE

Primary predicate device	**510 (k) Holder**	**510 (k) No.**	
Plasma IQ	**Neauvia North America, Inc**	K192813	

DEVICE DESCRIPTION

Plexr Plus 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 high frequency generator housed in an electrosurgical unit (handpiece) that ionizes the gas particles in the air. A stainless steel straight disposable active sterilized tip is not available with the system and is not supplied by the company. Three cordless handpieces with three fixed powers are charged in a docking/charging station prior to use.

Performance Testing and data

The following performance testing was conducted to prove compliance with performance requirements and support substantial equivalence:

Test	Objective	Result
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

Laboratory and performance tests were executed to ensure that the device functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

INDICATIONS FOR USE STATEMENT

Plexr Plus is used in the removal and destruction of skin lesions and coagulation of tissue.

SUBSTANTIAL EQUIVALENCE

All information provided with the present submission supports the substantial equivalence for PLEXR PLUS with the predicate device and its accessories that have identical characteristics and intended use and similar indication statement. In addition all clinical data and all performance tests that have been performed in accordance with the Standards for the Software Evaluation and for the Electrical and Electromagnetic Safety test, demonstrate PLEXR PLUS's safety and effectiveness for its intended use.

The following matrix illustrates the equivalencies of PLEXR PLUS, as well as the substantial equivalent predicate device.

PREDICATE DEVICES COMPARISON CHART

Table 1

COMPARISON CHART PLEXR PLUS			
	GMV S.r.l. PLEXR PLUS New Device	**Berger & Kraft** **PLASMA IQ** Predicate device	**Explanation of Differences between the devices**
"K" NUMBERS	**K210693**	**K192813**	
Proprietary name	**PLEXR PLUS**	**PLASMA IQ**	
CFR Section	878.4400	878.4400	none
Pro-code	GEI	GEI	none
Intended Use	Intended for use during non-invasive surgery. Is intended for use only in professional health care settings.	Intended for use during non-invasive surgery. Is intended for use only in professional health care settings.	Same intended use
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	Same indications for use
Mode of operation	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Same mechanism of action
Output	Monopolar	Monopolar	Same kind of output
Power Supply	100-240VAC 50/60Hz	110-250 VAC 50/60 Hz	Same power input parameters
Frequency	80 kHz	40 kHz	The output frequency is substantially the same in the electromagnetic spectrum. The minimal difference does not impact the efficacy of safety at all.
Max Output Power	2 W	5 W	The output power is not linear, and it is calculated as $P=V^2/R$, so 3 W of difference is not impacting the efficacy and the safety of the device.
Output	60,000 Ω	54,000 Ω	The output impedance is

Impedance			substantially the same.
Wave form			The waveform is sinusoidal for both the devices with similar amplitudes and frequencies.
System Components	System consists of a docking station and three handpieces	System consists of a handpiece that incorporates the electrosurgical generator unit, docking station, and an active electrode.	Plasma IQ presents one wireless handpiece with two buttons for choosing the fixed power output. Plexr Plus has three different wireless handpieces with a fixed power each. The operation is the same, just the configuration is different.
Tips	Needle electrode	Needle electrode	Same
Raw Materials	Tips: stainless steel Box and Handpieces: ABS	Tips: stainless steel Box and Handpieces: ABS	Same
Electrical Safety Standards	Complies with IEC60601-1, IEC60601-1-2, IEC60601-2-2	Complies with IEC60601-1, IEC60601-1-2, IEC60601-2-2	Same

TECHNICAL CHARACTERISTICS

A comparison of the technological characteristics of PLEXR PLUS and the predicate device has been performed. The results of this comparison demonstrate that the technologic characteristics and the operating principle of PLEXR PLUS are the same or very similar to those of the claimed predicate device. Where any differences arise from the analysis of the predicate device characteristics and those of the device subject of this submission, the clinical data evaluated from scientific publications give scientific evidence of the safety and the effectiveness of PLEXR PLUS. The system was evaluated and found compliant with IEC 60601-1 for electrical safety, IEC 60601-1-2 for IEC60601-1-2, IEC60601-2-2, and 10993-1 for biocompatibility of the treatment tips. Verification and validation data show that the device meets all product specifications.

CONCLUSION

Based on the foregoing, the PLEXR PLUS is substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510(k) submission. Safety and effectiveness were reasonably assured, justifying 510 (k) clearance.