October 27, 2023

GCS Co. Limited
℅ Su Kyung Park
Director
Compliance Insight
497 Circle Freeway Dr. Unit 230
West Chester, Ohio 45246

Re: K220493
Trade/Device Name: Plaxpot Multi Plasma
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: QVJ
Dated: [NOTE: Use date of most recent supplement]
Received: September 29, 2023

Dear Su Kyung Park:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.10.27 16:19:00 -04'00'

Mark Trumbore, 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)*
K220493

Device Name
PLAXPOT™ MULTI PLASMA

Indications for Use *(Describe)*
PLAXPOT™ MULTI PLASMA 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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510(k) Summary

5.1 General Information

Preparation Date: 18 February 2022

Revision Date: 26 October 2023

Submitter/Holder

Su Kyung, Park

Director

GCS Co., Ltd.
#1008, 555, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea
Tel: 82-2-555-1536 Fax : 82-2-3142-7670
Email: kara21c@gcsgroup.co.kr

Website: http://www.bestgcs.com/

Primary Contact

Cynthia Ipach
President/CEO

Email: cipach@compliance-insight.com

Office +1 513-860-3512 ext. 306
Compliance Insight
497 Circle Freeway Dr Suite 230. Cincinnati, OH 45246

5.2 Regulatory Information

Subject Device Trade Name	PLAXPOT™ MULTI PLASMA
Classification Name	Low Power Electrosurgical Devices For Skin Lesion Destruction
Device Classification	II
Regulation Description	Electrosurgical cutting and coagulation device and accessories
FDA Product Code	QVJ
CFR References	21 CFR 878.4400
Review Panel	General & Plastic Surgery

5.3 Identification of Predicate Devices

The primary predicate device for PLAXPOT™ MULTI PLASMA is the SubNovii Advanced Plasma Technology (K201738) and the reference device is Plasma IQ (K192813).

5.4 Subject Device Description

PLAXPOT™ MULTI PLASMA is a device that consists of a handpiece which is the main body and a charger (charging cradle, and power adapter). The high frequency current is exposed to the air and the air is ionized. The electrode tip can perform treatment without direct contact with the tissue.

After the power is applied through the internal battery, the mode is set and the Shot button is pressed, a high voltage alternating current pulse is released according to the set value, and the air is ionized to form a plasma arc.

This device uses plasma energy. This causes excess skin tissue to shrink and sublimate (direct passage from the solid to the gaseous state of matter) without affecting the deeper skin layers. The difference in potential distance between device's handpiece and the skin represents the area where the voltaic arc will take place. In this gap, the gases in the air are ionized, thus Plasma is generated. The tissues touched by plasma "sublime" without heat transfer to other unwanted tissues.

5.5 Indications for Use

PLAXPOT™ MULTI PLASMA is intended for the removal and destruction of skin lesions and coagulation of tissue.

5.6 Substantial Equivalence Discussion

In Table 1 on the following page please find a characteristics comparison summary. The review of the indications for use and comparison characteristics provided in **Table 1** demonstrate that PLAXPOT™ MULTI PLASMA is substantially equivalent to the primary predicate device, the SubNovii Advanced Plasma Technology K201738.

Table 1. Summary Comparison of Characteristics

Device Characteristics	**Proposed Device**	**Primary Predicate**	**Reference Device**
Product Name	PLAXPOT™ MULTI PLASMA	SubNovii Advanced Plasma Technology	Plasma IQ
510(k)	K220493	K201738	K192813
Manufacturer	GCS Co. Ltd.	Cartessa Aesthetics	Neauvia North America
FDA Product Code	QVJ	GEI	GEI
CFR Reference	878.4400	878.4400	878.4400
Device Class	II	II	II
Prescription or OTC	Prescription	Prescription	Prescription
Implanted Device	No	No	No
Indications for Use Statement	PLAXPOT™ MULTI PLASMA is intended for the removal and destruction of skin lesions and coagulation of tissue.	The SubNovii is intended for the removal and destruction of skin lesions and coagulation of tissue.	Plasma IQ is used in the removal and destruction of skin lesions and coagulation of tissue.
Mode of Operation	Plasma high frequency current ionizing the air creating a plasma stream.	Plasma radiofrequency energy ionizes the air creating a plasma stream.	Plasma radiofrequency energy ionizes the air creating a plasma stream.

Output Mode	Continuous	Continuous	Continuous
Energy Type	High Frequency	High Frequency	High Frequency
Power Level	3 modes at 0.7W, 1W, 2W	Max 5W	Max 5W
Reusable or Single Use	Reusable	Reusable	Reusable
Output	Monopolar	Monopolar	Monopolar
Max Power Output	3W	5W	5W
Power Supply	Internal Rechargeable Lithium Ion Battery 7.4 VDC 1000mAh	Internal Rechargeable Lithium Ion Battery 11.1 VDC	Internal Rechargeable Lithium Ion Battery 11.1 VDC
Frequency	70 kHz	40kHz	40kHz
System Components	A handpiece that incorporates the electrosurgical generator unit, OLED display, software, and docking station.	A handpiece that incorporates the electrosurgical generator unit, docking station and an active electrode.	A handpiece that incorporates the electrosurgical generator unit, docking station and an active electrode.
Electrical Safety Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Software	Yes	No	No
Software Compliance	IEC 62304	N/A	N/A

5.7 Sterilization and Shelf Life

The PLAXPOT™ MULTI PLASMA is sold non-sterile.

Shelf-life is not applicable because of low likelihood of time-dependent product degradation.

5.8 Performance Testing - Bench

Performance bench tests of PLAXPOT™ MULTI PLASMA have been performed, see **Table 2**. The results from the performance bench testing demonstrate that PLAXPOT™ MULTI PLASMA has met the functional requirements and is substantially equivalent to the predicate device. Performance bench testing is provided in detail.

Table 2. Performance Testing Summary

Study	Attachment	Test Method	Results
Basic Safety and Essential Performance	18-3	EN 60601-1:2006+A1:2013 or EN 60601-1:2006+A12:2014 and test report IEC60601_1K	Pass
Manufacturer Technical File	18-5	N/A	Pass
EMC Test	18-6	IEC 60601-1-2:2014	Pass
EMC Test	18-7	IEC 60601-1-2:2014	Pass
Thermal Effects Test	NA	FDA Submissions for Electrosurgical Devices for General Surgery	Pass

5.9 Conclusion

The subject device PLAXPOT™ MULTI PLASMA has the same technology, principle of operation, indications for use and technical specifications as the primary predicate device Subnovii and the reference device Plasma IQ. PLAXPOT™ MULTI PLASMA shares a substantially equivalent design, indications for use and technology (i.e. features, materials, and principles of operation) as the predicate device and no new elements pertaining to safety or effectiveness have been identified. Performance test results demonstrate that the subject device can perform the same intended use as safely as the predicate and reference devices. Therefore, the subject device is substantially equivalent to the predicate.