November 8, 2024

Guangzhou Aimira Innovation Technology Co, Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K242286
Trade/Device Name: Superflow Prime Treatment System (ASP-1M)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 2, 2024
Received: August 2, 2024

Dear Ray Wang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.08 13:44:29 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242286

Device Name

Superflow Prime Treatment System (ASP-1M)

Indications for Use *(Describe)*

Superflow Prime Treatment System 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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The assigned 510(k) Number: _____

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Submission: 2024/08/02

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Superflow Prime Treatment System

Common Name: Electrosurgical Cutting and Coagulation Device and Accessories

Regulatory Information
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
Classification: II

510(k) Summary

Product Code: GEI
Regulation Number: 878.4400
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K210693
Product Name: PLEXR PLUS
Manufacturer: GMV S.r.l.

6. Device Description:

AIMIRA SFP consists of Three modules, the main body, a multi-spectral skin camera, and a plasma skin treatment handpiece.

The main body includes a main cabinet, a touch screen display, a vacuum system, computer control system and power supply unit. The system runs on AiMIRA SFP software ASP-1M.

The skin camera consists of multi-spectral imaging optics, and an electronic control circuit.

The plasma skin treatment handpiece consists of high voltage plasma discharge circuit, high precision control electronics, a single patient use treatment probe unit, rechargeable battery system for power supply, and a wireless communication circuit to communicate with the computer in main body.

A vacuum and illumination system are integrated into AIMIRA SFP to facilitate the treatment process. There could be a small amount of smoke with burning smell associated with the plasmatic skin treatment process. The included super quiet high flow vacuum system with HEPA filters can efficiently remove the smoke and smell to provide a more comfortable treatment environment. A specially designed lighting system is also integrated at the vacuum head to provide soft and flush illumination around the treatment area.

A multi-spectral imaging (MSI) camera is also into AIMIRA SFP system. The purpose of the MSI camera is to provide the doctor an imaging tool to record the patient's skin conditions before and after treatments as part of the patient's treatment data record.

7. Indication For Use Statement:

Superflow Prime Treatment System is used in the removal and destruction of skin lesions and coagulation of tissue.

8. Substantially Equivalent (SE) Comparison

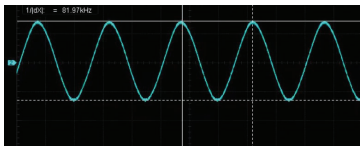
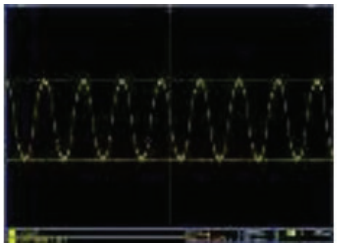
Table 1 General Comparison

Item	Proposed Device	Predicate Device K210693	Remark
Device Name	Superflow Prime Treatment System	Plexr Plus	/
Classification Regulation	21 CFR 878.4400	21 CFR 878.4400	SAME
Classification Panel	General & Plastic	General & Plastic	SAME

510(k) Summary

Class	II	II	SAME
Product Code	GEI	GEI	SAME
Common Name	Electrosurgical Cutting and Coagulation Device and Accessories	Electrosurgical Cutting and Coagulation Device and Accessories	SAME
Indication for use	Superflow Prime Treatment System is used in the removal and destruction of skin lesions and coagulation of tissue.	Plexr Plus is used in the removal and destruction of skin lesions and coagulation of tissue.	SAME
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
Prescription use or not	Prescription use	Prescription use	SAME

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Mode of operation	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	Plasma Radiofrequency energy ionizes the air creating a Plasma stream	SAME
Output	Monopolar	Monopolar	SAME
Power Supply	110-240 VAC, 50/60Hz	100-240VAC 50/60Hz	Analysis
Frequency	80 KHz	80 kHz	SAME
Max Output Power	2 W	2 W	SAME
Output Impedance	60 kΩ	60,000 Ω	SAME
Wave form			SAME
System Components	System consists of three modules: the main body (includes a main cabinet, a touch screen display, a vacuum system, computer control system and power supply unit), a multi-spectral skin camera, and a plasma skin treatment handpiece.	System consists of a docking station and three handpieces	Analysis

Tips	Needle electrode	Needle electrode	SAME
Raw Materials	Tips: stainless steel	Tips: stainless steel Box and Handpieces: ABS	SAME

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark
Biocompatibility			
Cytotoxicity	No Cytotoxicity	10993-1 for biocompatibility of the treatment tips	SAME
Irritation	No evidence of Irritation		SAME
Sensitization	No evidence of Sensitization		SAME

Analysis：

Different - Power Supply

The power supply for the proposed device is different from the predicate device. However, electrical safety and EMC test has been conducted on the proposed device and the test result show that the device can work normally under this power supply. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Different - System Components

The proposed device has different system components with the predicate device.

- Different of the treatment hadpiece numbers:

The system components of the predicate device is consists of docking station and three treatment handpieces. And the proposed device just has one plasma skin treatment handpiece. Although the number of treatment handpiece varies, the proposed device and the predicate device share the same working principle (*They are all treats patients' skin with plasma discharge. A treatment method called plasma sublimation, which causes controlled skin damage through the generation of an electrical arc. They are all ionizes the gas particles in the air and ionizes air molecules into plasma state*) and technologic characteristics (*including performance parameters, frequency, maximum output power, output impedance, etc.*).

Therefore, we believe that although the number of treatment handpieces for the proposed device and the predicate device is different, we can achieve the same intended use and will not affect the effectiveness or new safety risk creating based on the same working principle and the same technologic characteristics.

- Different of vacuum system:

The main body of the proposed device is included a vacuum and illumination system.

This vacuum system of proposed device is only used for remove the smoke and smell which is associated with the plasmatic skin treatment process to provide a more comfortable treatment environment. The illumination system of proposed device is only used for provide soft and flush illumination around the treatment area.

The vacuum and illumination system of the proposed device is only serves as an auxiliary function. It is not an indispensable function or component in the process of achieving the intended use of the proposed device, nor will it have any impact on the realization of the intended use.

Therefore, we think this vacuum and illumination system will not affect the safety and effectiveness of the proposed device.

- Different of skin camera:

The proposed device has a multi-spectral skin camera.

The multi-spectral skin camera of proposed device is only used for provide the doctor an imaging tool to record the patient's skin conditions before and after treatments as part of the patient's treatment data record. And the image capturing process is also a optional function that depends on the physician. It is not an indispensable function in the process of achieving the intended use. Please refer to the Page 36 (use of skin camera) of the User Manual.

In addition, the material expected to come into contact with the human body for this component is soft silica gel. For this material, we have also conducted three biocompatibility tests according to the 10993-1: Cytotoxicity, Irritation, and Sensitization.

Therefore, we think that the multi-spectral skin camera of proposed device will not affect the safety and effectiveness.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 60601-1-6 2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- IEC 62133-1: 2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed
- AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to the legally marketed predicate device Plexr Plus (K210693).