Triworks Group SRL
℅ Matthew Brulport
President
NEOconcepts LLC
2773 Alum Crossing Dr.
Lewis Center, Ohio 43035

July 7, 2022

Re: K212472
Trade/Device Name: AgeJet
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 17, 2022
Received: June 21, 2022

Dear Matthew Brulport:

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,

for

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)*
K212472

Device Name
AgeJet System

Indications for Use *(Describe)*
The AgeJet system is an electrosurgical device and is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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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K212472. 510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Submitter's Name: Lorenzo Berchicci

Company: Triworks Group srl

Submitter's Address: via Leone Belpulsi, 3 - 86100 Campobasso (CB) Operational Office: via Don Giuseppe Mucciardi, 5 86020 Campochiaro (CB) - Italy.

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Date Prepared: July 4th 2022

Device Trade Name: AgeJet

Device Common name: Electrosurgical Device

Device Classification Information:

Regulation Number	Device Classification name	Device Class	Product Code	Classification Panel	Type
21 CFR 878.4400	Electrosurgical cutting and coagulation device and accessories	Class 2	GEI	General & Plastic Surgery	Traditional 510 (k)

Device Description
The AgeJet system is an electro-surgical device intended for use in dermatological applications in hospital and clinics.
The AgeJet system comprises of the following.

AgeJet Generator
The wheeled unit powered by120 VAC (available 110-240 VAC according to the market) with standard wall socket.

Footswitch
This is a single pedal type for activation of the output.

Handpiece/Cable Assembly
The handpiece and the cable assembled can be easily plugged and unplugged from the AgeJet Generator as reported in the User Manual. The handpiece has an integral key that is used by the generator to ensure it is not used beyond its operational life.

Handpiece holder
The handpiece holder with the thermal sensor is connected to the generator according to the User Manual.

Procedure Pack
Comprising one or more disposable nozzles that is connected to the handpiece, and which have an integral key that is used by the generator to ensure it is not used beyond its operational life.

Nitrogen Gas Cylinder & Pressure regulator
These are not supplied as a part of the AgeJet system. Only medical grade nitrogen (99.5% purity) should be used. The Nitrogen tank is specified as 534mm high by 106mm diameter, a capacity of 560 litres at 2200psiG.

Cylinder Holder Plate Kit
This kit includes screws, plate, cable holder shaft and cable tray. Please refer to the User Manual for the installation procedures.

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Intended Use

The AgeJet system is an electrosurgical device used in dermatologic and general surgical for electro coagulation and hemostasis.

Plasma energy is delivered to the tissue and energy is rapidly transferred to the tissue surface. As the plasma energy passes through the tissue it generates an electrothermal reaction which is capable of coagulating tissue.

Indications for Use

The AgeJet system is an electrosurgical device that can be used in the treatment of dermatological and general surgical conditions through electro coagulation and hemostasis.

Predicate device(s)

The AgeJet system is substantially equivalent to the PlaDuo system K201735.The AgeJet system is predicated against Pladuo as both devices are electrosurgical devices intended for the treatment of dermatological and general surgical conditions through electro coagulation and hemostasis.

The key technological characteristics of the subject device and predicate device are summarized in the following table;

Characteristics	Proposed device AgeJet Device K212472	PlaDuo System K201735	Degree of equivalence
Manufacturer name & address.	Triworks SRL Via S. Rocco, 58 Bis 86037 Palata CB Italy	SheNB Co Ltd Seongsui-ro, 148 Seongdong-gu Seoul South Korea	N/A
Device Trade Name	AgeJet	PlaDuo	N/A
Mode of Operation	Nitrogen Gas	Nitrogen Gas	Identical
Intended use	An electrosurgical device used in dermatologic and general surgical for electro coagulation and hemostasis.	An electrosurgical device used in dermatologic and general surgical for electro coagulation and hemostasis.	Identical
Principle of Operation	Plasma energy is delivered to the skin and the energy is rapidly transferred to the skin surface. As the plasma energy passes through the tissue it generates an electrothermal reaction which is capable of coagulating tissue.	Plasma energy is delivered to the skin and the energy is rapidly transferred to the skin surface. As the plasma energy passes through the tissue it generates an electrothermal reaction which is capable of coagulating tissue.	Identical
Frequency	2.45Ghz	2.45Ghz	Identical
Modulation	Pulsed Carrier wave	Pulsed Carrier Wave	Identical
Max Power (w) overall	260W (260-160 = 100W)	100W	Identical
Cooling compressor power (W)	160W	Not Applicable	PlaDuo does not have patient cooling system
Maximum Magnetron output	900W (AgeJet uses only 11% of total at all energy levels)	Not known	-
Output Energy (joule)	0.5-4J	0.5- 4J	Identical

Characteristics	Proposed device AgeJet Device K212472	PlaDuo System K201735	Degree of equivalence
Repetition rate	1-3 Hz	1-3Hz	Identical
Pulse Width (single pulse)	4 to 15ms	5 to 15ms	Equivalent
Depth of Thermal effect	Up to 350 microns	Up to 400 microns	Equivalent
Gas requirement	Medical grade Nitrogen 99.9%	Medical grade Nitrogen 99.9%	Identical
Electrical supply Voltage	AC 110 – 240 Volts 50/60 Hz	AC 100 – 230 Volts 50/60 Hz	Equivalent
Mains connection	Detachable Power Cord to IEC type appliance inlet Mains Switch controlled ON/OFF Operation	Detachable Power Cord to IEC type appliance inlet Mains Switch controlled ON/OFF Operation	Identical
Device classification	Class II	Class II	Identical
Regulation number	21 CFR 878.4400	21 CFR 878.4400	Identical
Rx/OTC	RX	RX	Identical
Device classification name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories	Identical
Device product code, classification name	GEI	GEI	Identical

Similarities and Differences between the subject and predicate device:
Key Similarities

The AgeJet system is substantially equivalent to the PlaDuo System (K201735), as both are electrosurgical devices used in dermatologic and general surgical for electro coagulation and hemostasis.

Both systems exact their effect on the tissue through the same mechanism. Plasma energy is delivered to the skin and the energy is rapidly transferred to the skin surface. As the plasma energy passes through the tissue it generates an electrothermal reaction which is capable of coagulating tissue.

The AgeJet system and PlaDuo have the same principle of operation, mode of action and equivalent energy outputs to a maximum of 4Joule.

Both devices have similar incremental precision settings of 0.25J and 0.1 Joule respectively.

The AgeJet, and PlaDuo systems have identical treatment pulse repetition rates 1.0 to 3.0 Hz.

The pulse of UHF required to generate a given energy level or single Pulse width are equivalent.

The RF output frequency of the proposed device is identical to the predicate device 2.45Ghz.

Differences

There are no significant differences in terms of the key device parameters that raise questions in terms of safety and efficacy.
Where there are differences between the AgeJet system and the predicate device, these occur in terms of the devices services which do not alter efficacy parameters of the device and where necessary have been tested and conform to relevant standards.

Electrical safety and safety standards

To demonstrate safety and effectiveness of the AgeJet system and to demonstrate substantial equivalence to the predicate devices, Triworks Group srl has completed several non-clinical performance tests. The AgeJet meets established requirements for overall design, electrical safety, software validation and usability studies confirming that the design outputs meet design input requirements and established specifications.
The AgeJet system successfully passed testing per internal verification/validation requirements and national/international standards illustrated below:
EN 60601-1:2006
EN 60601-1-2:2015
EN 60601-2-2:2018

Other Non-Clinical Performance testing

To demonstrate safety and effectiveness and substantial equivalence the AgeJet system has undergone several non-clinical performance tests in line with recognized standards in terms of general requirements, biocompatibility, and software.
The following non-clinical performance data is provided in support of the substantial equivalence determination.

Biocompatibility

Materials used in the AgeJet system have been evaluated in respect to material composition, use and patient/user contact according to ISO 10993-1: 2018.

Software verification and validation testing

Software has been classified in accordance with EN 62304:2015 and Guidance for the Content of Premarket Submissions for Software Contained in Medical

Devices Guidance for Industry and FDA Staff May 2005. Verification and Validation in accordance with the software risk concern provides evidence that all design specifications were met.

Performance testing

Performance tests were conducted to assess the performance characteristics of AgeJet and ensure its functionality and stability when used in accordance with the manufacturer indications. The device was tested to verify that the output power value falls within the manufacturers specified range, thus ensuring the efficiency of the device. The results show that AgeJet works as expected, according to the manufacturers specifications.

In vitro testing of the AgeJET nitrogen plasma device was performed on four different types of tissue as per Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (DOC-FDA-2014-D-0217): liver, kidney, muscle, and skin. Treatment settings included the three power levels, low (1 J), medium (2 J) and maximum (4 J), at the minimum clinically relevant distance (5 mm) from the tissue surface and at temperature close to physiological 37^{o}C. All test settings were triplicated and collected biopsy samples analyzed by H&E histology method. The testing demonstrated that the treatments produced clearly detectable thermal damage profiles in treated tissues with depths ranging from a few tens of microns up to a few hundred microns for a single pulse treatment and several stacked pulses, respectively. The study demonstrated the ability of the AgeJet device to achieve consistent thermal damage profiles in line with the target treatment and comparable to the profiles produced by the predicate device. Thus, it can be concluded that treatment by such device at the appropriate testing settings will possess a desirable clinical treatment effect.

Statement of Substantial Equivalence:

513(i) of the FD&C Act (21 U.S.C. 360c(i) states that for substantial equivalence a proposed device is required to have the same intended use and equivalent technological characteristics as the predicate device. Where there are differences in technological characteristics, these can be negated by appropriate clinical or non-clinical performance testing demonstrating that the proposed device is as safe and effective as the predicate device, and that the proposed device does not

raise any different questions of safety and effectiveness than the predicate device for the same intended use.
Triworks Group srl has demonstrated that the AgeJet device has the same intended use as the predicate device, employs equivalent technological characteristics, and has similar thermal effects in tissue. Where there are minor differences, these occur only in the basic services of the device. The sponsor demonstrates that the device does not pose any additional questions regarding safety and efficacy relative to the predicate.
Therefore, the AgeJet system, as designed, and manufactured, has been demonstrated to be substantially equivalent to the referenced predicate, the PlaDuo System K201735.