January 12, 2023

Energist Limited
Graham Booth
Chief Technical Officer
2 Park Pavilions, Clos Llyn Cwm
Enterprise Park
Swansea, SA6 8QY
United Kingdom

Re: K221873
Trade/Device Name: NeoGen PSR System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 08, 2022
Received: December 13, 2022

Dear Graham Booth:

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,

Colin K. Chen -S

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)*
K221873

Device Name

NeoGen PSR Plasma Skin Resurfacing Device

Indications for Use *(Describe)*

When used with the 5mm nozzle the NeoGen PSR System is intended for treatment of the following dermatological conditions :

- Treatment of wrinkles and rhytids
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrheic Keratosis
- Acne Scars

When used with the 25mm nozzle, the NeoGen PSR System is intended for coagulation of tissue in dermatological procedures.

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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Revision: ..... B **Date:** ..... 12 January 2023

Document Title: ..... 510(k) Summary (Per 21 CFR 807.92)

Subject: ..... NeoGen PSR System 510(k) Application

510(k) Number K221873

Submitter Name: ..... Energist Limited

Establishment Registration No: 3007353760

Submitter Address: ..... 2 Park Pavilions, Clos Llyn Cwm, Swansea Enterprise Park, Swansea, SA6 8QY, United Kingdom.

Contact Person: ..... Graham Booth – Chief Technical Officer
Email: gbooth@energist.com

Telephone Number: ..... +44 1792 798768

Revision Date: ..... 11 January 2023

Device Trade Name: ..... NeoGen PSR System

Common Name: ..... Electrosurgical Device

Device Classification: ..... Electrosurgical cutting and coagulation device and accessories Class II

Product Code: ..... GEI (21 CFR 878.4400)

DEVICE DESCRIPTION

System Elements

The system comprises the following major elements:

- The Energist NeoGen PSR generator. This incorporates a source of Ultra High Frequency (UHF) energy and the gas control system required to support creation of nitrogen plasma;
- A Footswitch – single pedal type for activation of the plasma output.
- A handpiece that connects to the generator via an umbilical, which incorporates electrical and gas connections. The handpiece incorporates a finger-operated button switch that can be used to activate the plasma as an alternative to the footswitch.
- A Procedure Pack, comprising one or more limited life disposable tips (nozzles) through which the plasma is delivered. These are a snap fit to the distal end of the handpiece;
- A gas supply system – principally a nitrogen gas cylinder and a regulator assembly;
- A bespoke trolley which provides a secure, mobile platform for the generator, handpiece, gas cylinder (plus a spare cylinder) and gas regulator assembly.

Principle of Operation

The NeoGen PSR delivers controlled thermal energy to the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis. The body's natural healing process causes the damaged skin to be replaced with new, fresh, growth – thus resulting in improvement of the appearance and effects of the indicated conditions.

The thermal energy emitted by the system is in the form of a nitrogen gas plasma. This is created by subjecting pressurised nitrogen gas to a high level of Ultra High Frequency (UHF) energy. This process takes place in the handpiece of the device, more specifically in a resonator tube, or "nozzle", the distal end of which is directed at the skin surface. The handpiece is connected to the main generator unit via an "umbilical", which incorporates a gas supply tube and a cable capable of conducting the UHF energy. It also incorporates a cable for control signals between the handpiece and the generator unit to support the action of a control button and gas solenoid valve, plus secure identification and "counter" elements in the nozzle and the handpiece itself. The plasma is created in short pulses, approximately 5 to 15 milli-seconds in duration. Automatic adjustment of the UHF power level and pulse duration to the handpiece enables control of tissue effects by altering the amount of energy delivered by the plasma to the skin surface for each pulse. In practice, the energy per pulse can be varied from 1.0 to 4.0 Joules when the system is used with the 5mm nozzle, and from 0.5 to 0.8 Joules when used with the 25mm nozzle. The system can be configured to automatically generate a series of pulses at set intervals to allow the operator to move the handpiece over the surface of the skin at a steady speed to achieve a uniform effect. Alternatively, the pulses can be manually triggered – either by pressing the control button on the handpiece, or by depressing a footswitch, according to operator preference.

The nozzles are limited-life components which are a snap-fit onto the distal end of the handpiece and are easily replaced. A stand-off incorporated in the nozzle allows the distance from the skin surface to be accurately determined. The separation distance influences the amount of energy impacting the skin surface. NeoGen PSR systems are capable of supporting the use of nozzles with 5mm standoff, as well as 25mm. This is as per the Rhytec Portrait PSR3, which was the legally marketed predicate device cited when the NeoGen PSR was originally cleared under K132754.

Handpiece usage is also monitored and the system limits use to guard against unexpected failure due to degradation with use over time. The handpiece is user replaceable.

The generator incorporates a large colour touchscreen display supporting a Graphical User Interface that clearly conveys information to the operator and allows settings to be made readily and conveniently.

Intended Use/ Indications For Use

When used with the 5mm nozzle the NeoGen PSR System is intended for treatment of the following dermatological conditions:

- Treatment of wrinkles and rhytids
- Superficial skin lesions
- Actinic Keratosis
- Viral Papillomata
- Seborrheic Keratosis
- Acne Scars

When used with the 25mm nozzle, the NeoGen PSR System is intended for coagulation of tissue in dermatological procedures.

Intended Use Environment

The system is intended for professional use by trained and duly qualified medical practitioners in hospitals and clinics. It must not be used in domestic, industrial or outdoor locations, or in critical care environments.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the current Energist NeoGen PSR system with 25mm nozzle option that is the subject of this K221873 submission and the predicate PSR system originally cleared under K132754 are summarised and compared in the table below:

Parameter	K132754 Predicate NeoGen PSR system	K222873 Subject NeoGen PSR system with 25mm option
Energy setting Displayed Values Precision	0.1 Joule	0.1 Joule
Max Output Energy	4 Joules	4 Joules
Treatment Pulse Repetition Rate	Repeat Pulse mode: 1.0 to 2.5 Hz Single Pulse mode: User determined.	Repeat Pulse mode: 1.0 to 2.5 Hz Single Pulse mode: User determined.
Output Pulse Width	5.2 to 15.4 ms	5.2 to 15.4 ms
Safety Classification (per EN/ISO 60601-1)	Class 1 (the Generator requires connection to a Protective Earth).	Class 1 (the Generator requires connection to a Protective Earth).
FDA Regulatory Classification	Class II	Class II
FDA Regulation Number	21 CFR 878.4400	21 CFR 878.4400
FDA Regulation Name	Electrosurgical cutting and coagulation device and accessories.	Electrosurgical cutting and coagulation device and accessories.
FDA Product Code	GEI	GEI
EU MDR Classification	Risk Class IIb	Risk Class IIb
Applied Parts	Type BF(not defibrillator proof)	Type BF(not defibrillator proof)
Duty Cycle	20 seconds on, 10 seconds off, for a maximum of 50 plasma pulses at the 2.5Hz maximum rate	20 seconds on, 10 seconds off, for a maximum of 50 plasma pulses at the 2.5Hz maximum rate
Operational Ambient Temperature Range	10 to 30 °C.	10 to 30 °C.
Operational Humidity	30 to 75% RH	30 to 75 RH
Atmospheric Pressure	700 to 1060 hPa.	700 to 1060 hPa.
Power Requirements Voltage: Current: Power Consumption:	– 100-230 Vrms, 50-60Hz, 1 ph. – 6.5A max. – ≤650 VA	– 100-230 Vrms, 50-60Hz, 1 ph. – 6.5A max. – ≤650 VA
Inlet Safety Fuses Quantity, Size: Type: Rating: Approvals: Breaking Capacity	– 2x, 20mm x 5mm – Time Lag (T) type – 6.3A, 250 VAC – UL Listed – 1500A @250VAC	– 2x, 20mm x 5mm – Time Lag (T) type – 6.3A, 250 VAC – UL Listed – 1500A @250VAC

Parameter	K132754 Predicate NeoGen PSR system	K222873 Subject NeoGen PSR system with 25mm option
Mains Connection Inlet type: Power Cord: Mains Switch:	IEC 60320 type C14 IEC 60320 type C13 (local plug a/r) Double Pole, integral with inlet	IEC 60320 type C14 IEC 60320 type C13 (local plug a/r) Double Pole, integral with inlet
RF Output Frequency	2450 to 2480 MHz (2470 MHz typ). No sub-harmonics	2450 to 2480 MHz (2470 MHz typ). No sub-harmonics
Modulation	Pulsed CW (Carrier Wave)	Pulsed CW (Carrier Wave)
Gas System	Commercially available medical grade nitrogen is supplied via a Regulator assembly included with the system to provide a feed to the Generator at 1.7Bar (nom.)	Commercially available medical grade nitrogen is supplied via a Regulator assembly included with the system to provide a feed to the Generator at 1.7Bar (nom.)
Footswitch	Medical type, rated 60V, 5A DC	Medical type, rated 60V, 5A DC
Trolley	Custom made 5-wheel trolley with locking wheels accommodates the Generator and 2 gas cylinders (including a spare). Meets stability requirements of IEC 60601-1.	Custom made 5-wheel trolley with locking wheels accommodates the Generator and 2 gas cylinders (including a spare). Meets stability requirements of IEC 60601-1.
Handpiece	Connecting to the Generator via a flexible umbilical, the Handpiece accommodates the nozzle, which is where the plasma is generated. Total number of shots is limited (electronically) to 250,000 after which the handpiece must be replaced.	Connecting to the Generator via a flexible umbilical, the Handpiece accommodates the nozzle, which is where the plasma is generated. Total number of shots is limited (electronically) to 250,000 after which the handpiece must be replaced.
Nozzles	5mm standoff version allows for delivery of plasma energy in the range 1.0 to 4.0 Joules.	5mm standoff version allows for delivery of plasma energy in the range 1.0 to 4.0 Joules. 25mm standoff option allows for delivery of plasma energy in the range 0.5 to 0.8 Joules.

With the exception of the 25mm nozzle option (highlighted in red) – clearance of which is the subject of this 510(k) submission – the technological characteristics of the predicate and subject devices are identical.

TESTS PERFORMED

A full description of tests carried out to confirm conformity to applicable standards is given in Energist document no. *DD0254 NeoGen PSR Compliance Summary Report [USA]*, included with this submission.

Note that the 25mm nozzle has been included in the scope of the assessments conducted (it has been made available in other markets since 2014). However, the choice of 5mm or 25mm nozzle does not materially impact safety or EMC.

A summary is given below.

Basic Safety

Representative samples of the NeoGen PSR system have been tested by an accredited third-party test organisation to demonstrate compliance with the following medical device safety standards: These tests have included assessment

60601-1 Basic Safety

Standard	ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 – Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
FDA Consensus Standard Recognition Number	19-4
Report Ref.	071-75945748-000TRF_CE_E (inc. attachment 1)
Issued By	TÜV SÜD, United Kingdom

60601-2-2 HF Surgical Equipment

Standard	IEC 60601-2-2:2017 - Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
FDA Consensus Standard Recognition Number	6-389
Report Ref.	071-75945748-000TRF_CE_E (attachment 2)
Issued By	TÜV SÜD, United Kingdom

Electro-Magnetic Compatibility

Representative samples of the NeoGen PSR system have been tested by an accredited third-party test organisation to demonstrate compliance with the following medical device EMC standards:

Standard	IEC 60601-1-2 - Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance -- Collateral Standard: Electromagnetic disturbances -- Requirements and tests
FDA Consensus Standard Recognition Number	19-8
Report Ref.	R18-4514A Is. 2
Issued By	Kiwa, United Kingdom

Performance Testing

Representative samples of the NeoGen PSR system have been tested by Energist Limited UK to demonstrate compliance with the user and functional performance requirements. Numerous documents are available, the “headline” ones being:

DD0133R NeoGen System Validation Report ;Overall System Requirements

SD0618R NeoGen System V&V Report *;*Software determined functionality

In respect of the 25mm nozzle specifically, please refer to the following document:

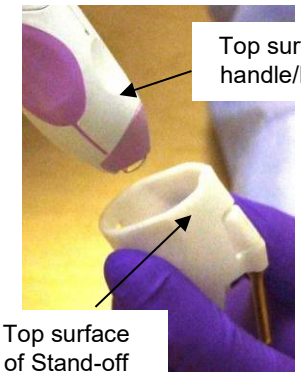
DD0246 NeoGen 25mm Nozzle - Safety & Efficacy Review.

TECHNOLOGY COMPARISON

This is a review of the differences between the 25mm standoff arrangements as cleared in K072394 for use with the Rhytec PSR^3, (the original predicate as cited in the K132754 submission for the NeoGen PSR), and those of the current 25mm nozzle that is the subject of this K221873 submission.

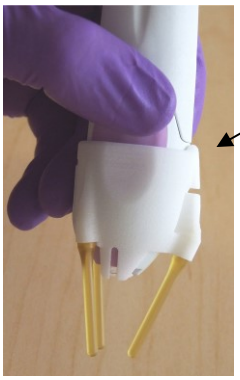
Rhytec 25mm Standoff

This took the form of an adapter that could be fitted over the standard nozzle. The below excerpt from Rhytec's instruction sheet for the standoff shows the fitting instructions, and also gives an idea of the physical appearance and characteristics.



Orientate Stand-off to the Nozzle noting alignment of top surfaces of each part

Engage the Stand-off onto the Nozzle



Stand-off correctly fitted onto the Nozzle

Essential characteristics of the Rhytec 25mm standoff are as follows:

Standoff Distance:	25mm
Service Life:	To be replaced after use with 10 nozzles
Energy Reduction Factor:	0.65
Patient Contacting Material:	Ultem
Spot Separation:	12mm
Energy Range:	0.65 to 1.0 Joule*

* The lower limit is determined by the minimum output level of the Portrait PSR^3 (1 Joule) and the Energy Reduction Factor (0.65). The maximum is that recommended in the IFU to prevent overheating of the tips, which could result in patient discomfort and damage to the standoff.

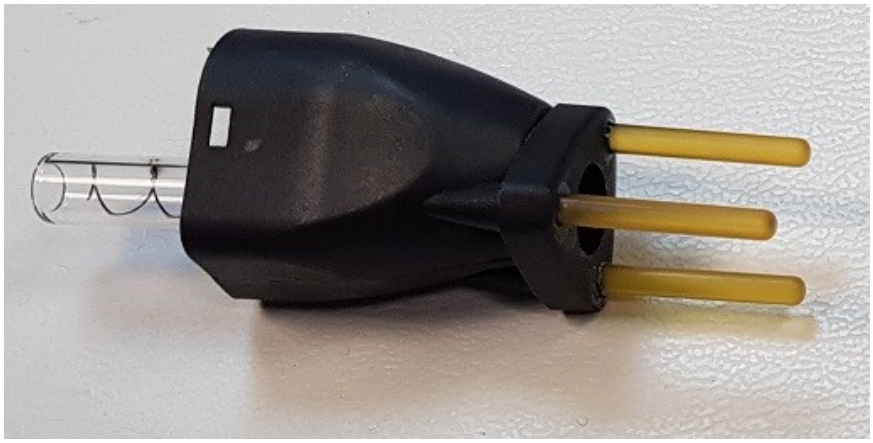
The Rhytec Portrait PSR^3 was a relatively basic device and was not able to detect the presence or absence of the adapter. It was therefore necessary for the operator to perform their own calculation of the effective energy reaching the skin surface, based on the reading on the numeric display.

The range of energy outputs available were:

PSR[3] Energy Setting (J):	1.0	1.1	1.2	1.3	1.4	1.5
Energy at Skin Surface (J):	0.65	0.7	0.8	0.85	0.9	1

NeoGen 25mm Nozzle

On the NeoGen device, the standoff is an integral part of the nozzle. It attaches to the distal end of the handpiece in the same manner as the 5mm nozzle. A picture of the device is shown below.



Essential characteristics of the NeoGen 25mm nozzle are as follows:

Standoff Distance: 25mm

Service Life: 9000 shots

Energy Reduction Factor: N/A

Patient Contacting Material: Ultem

Spot Separation: 12mm

Energy Range: 0.5 to 0.8 Joule (in 0.1J steps)

The main practical differences between the NeoGen 25mm nozzle and the Rhytec solution are:

- The NeoGen PSR automatically detects the presence of the 25mm nozzle and adjusts the on-screen energy settings to reflect the actual energy delivered to the skin surface. This reduces the burden on the operator, and the possibility of errors;
- It is not possible to exceed the maximum ratings of the nozzle in respect of energy level or rated lifetime;
- The possibility of the standoff being incorrectly fitted, or becoming detached, is reduced;
- Available energy levels differ. At such low levels the clinical differences are minimal however.

The main similarities are:

- Same spot size – treatment techniques therefore remain the same;
- Same material used for standoff – biocompatibility and thermal stability considerations therefore remain the same.

CONCLUSION

The comparison of Technological Characteristics and the results of the performance and compliance testing conducted demonstrate that the subject device is Substantially Equivalent to the predicate device as cleared in K132754, and that the 25mm nozzle is Substantially Equivalent to that of the Rhytec nozzle/25mm standoff combination as cleared under K072394.