May 24, 2024

Epimed International
% Robert Packard
President, Medical Device Academy
141 Sal Landrio Drive,
Crossroads Business Park
Johnstown, NY 12095

Re: K232632
Trade/Device Name: Racz Neurostat RF Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD
Dated: April 26, 2024
Received: April 26, 2024

Dear Robert Packard:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2024.05.24 17:13:00 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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)*
K232632

Device Name
Racz Neurstat RF Generator

Indications for Use *(Describe)*
The Racz Neurostat RF Generator is intended for lesioning of neural tissue. It is indicated for use in the peripheral nervous system. It is to be used with Epimed RF probes and cannula.

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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# 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

## I. SUBMITTER

Epimed International
141 Sal Landrio Dr. Crossroads Business Park
Johnstown, NY 12095
Tel: +1.518.725.0209 ext. 1300

Contact Person: Robert Packard
Date Prepared: May 24, 2024

## II. DEVICE

| | |
|---|---|
| Name of Device: | Racz Neurostat RF Generator |
| Classification Name: | Radiofrequency lesion generator |
| Regulation: | 21 CFR §882.4400 |
| Regulatory Class: | Class II |
| Product Classification Code: | GXD |

## III. PREDICATE DEVICE

| | |
|---|---|
| Predicate Manufacturer: | NeuroTherm, Inc. |
| Predicate Trade Name: | NT 2000 Lesioning Generator |
| Predicate 510(k): | K111576 |

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

The Racz Neruostat RF Generator is a touchscreen controlled Radio Frequency (RF) Generator used to lesion neural tissue for pain management. It has 4 outputs for delivering RF from a single source into the patient, it includes functions for nerve stimulation (Sensory and Motor), Continuous Thermal RF Lesioning, Pulsed RF Lesioning and Pulsed Dose RF Lesioning. The RF Energy is transmitted via each individual probe and a Neutral Electrode when in monopolar mode; or between probes when running in bipolar mode. The device will monitor the patient's impedance, probe temperature, along with the voltage and current of the RF Energy during a procedure.

## V. INDICATIONS FOR USE

The Racz Neurostat RF Generator is intended for lesioning of neural tissue. It is indicated for use in the peripheral nervous system. It is to be used with Epimed RF probes and cannula.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have identical indications for use. Both are intended for lesioning of neural tissue and for use in the peripheral nervous system.
- Materials – The predicate and subject device are made of equivalent materials. The patient contact materials of the subject device are found in the probe, which has already been 510(k) cleared.
- Design – The predicate and subject device have equivalent designs. Both devices supply continuous RF energy to the tissue causing the tissues surrounding the electrode to reach ablative temperatures.
- Energy Source – The predicate and subject devices both connect to mains power. Both are capable of delivering continuous RF energy at 460 kHz.
- Performance Testing – The predicate and subject device were tested against the applicable EMC and Electrical Safety IEC 60601 standards. The devices both underwent hardware performance testing to demonstrate that the hardware will function as intended through the expected lifetime of the device. Comparative lesion testing was performed to demonstrate performance equivalence compared against the predicate device. Software verification and validation testing were performed to ensure the generator met all relevant requirements. The subject device also conducted a usability test to validate the usability of the generator.

| | Racz Neurostat RF Generator | NeuroTherm NT 2000 Lesioning Generator – K111576 | Comments on SE |
|---|---|---|---|
| *Indications for Use* | The Racz Neurostat RF Generator is intended for lesioning of neural tissue.<br><br>It is indicated for use in the peripheral nervous system.<br><br>It is to be used with Epimed RF probes and cannula. | Intended for use for lesioning of neural tissue.<br><br>Indicated for use in the peripheral nervous system.<br><br>To be used only with FDA cleared NeuroTherm RF probes.<br><br>To be used only with FDA cleared Smith & Nephew SPINECATH and ACUTHERM catheters. | Equivalent indications for use. |
| *Power Output* | Max power output 98W split into 50W max per channel | Max power output 50W into 100 Ohms | Equivalent. Output per channel is the same |
| *RF Board Design* | Single board for all 4 channels using multiplexing | 1 board for each channel | |

| | | | |
|---|---|---|---|
| *Continuous RF Frequency* | 460 kHz | 460 kHz | Equivalent |
| *Stimulation – Sensory and Motor* | Yes | Yes | Equivalent |
| *Energy Delivered during multi channel RF treatment* | Continuous independent simultaneous energy delivery | Continuous independent simultaneous energy delivery | Equivalent |
| *Continuous Thermal* | Yes | Yes | Equivalent |
| *Pulsed RF* | Yes | Yes | Equivalent |
| *Monopolar* | 4 | 4 | Equivalent |
| *Bipolar* | Yes | Yes aka "dual" | Equivalent |
| *Printer* | No | Yes | Not a necessary or useful function to achieve intended use. |
| *Wireless Mouse* | No | No | Equivalent |
| *Touch Screen* | Yes | Full operation | Equivalent |
| *Excess Power Safety Feature* | Yes | Yes | Equivalent |
| *Excess Temperature Safety Feature* | Yes | Yes | Equivalent |
| *Footprint* | 279 x 368 x 203 mm (w x h x d) | 370 x 320 x 430 mm (w x h x d) | Smaller system is easier to move. |
| *Weight* | 12 lbs (6 kg) | 11.4 kg | Lighter system improves usability. |
| *Touchscreen Dimensions* | 15.4" Diagonal | 14" Diagonal | Larger screen increases usability of the interface. |
| *Electrical Safety/EMC* | IEC 60601 Compliant | IEC 60601 Compliant | Equivalent |

Testing Comparison

| | | | |
|---|---|---|---|
| *EMC and Electrical Safety Product Testing* | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-2-2 | IEC 60601 | Equivalent |
| *Hardware Performance Testing* | Testing was performed to demonstrate the hardware will function as intended through the expected lifetime of the device. | Bench testing. | Equivalent |
| *Comparative Lesion Testing* | Comparative lesion testing was performed to support substantial equivalence to the predicate device. | Not referenced in 510(k) summary. | N/A |
| *Software Verification and Validation* | Software verification and validation testing was performed to ensure the generator met all relevant requirements. | Software verification and validation testing. | Equivalent |

| | | | |
|---|---|---|---|
| *Usability* | Testing was performed to verify and validate the usability of the generator. | Not referenced in 510(k) summary. | N/A |

## VIII. CONCLUSIONS

The Racz Neurostat RF Generator is similar or the same as the predicate as follows:

- Technology
- Intended use/Indications for use
- Technical Specifications, or ranges of technical specifications
- Functional modes

The testing demonstrates that the subject device performs as well as the predicate device and complies with all of the applicable electrical safety and ECM tests. Therefore, it is concluded that the subject device is substantially equivalent to the predicate device.