March 15, 2023

RF Innovations, Inc
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K220122
Trade/Device Name: Apex 6
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD
Dated: April 27, 2022
Received: April 28, 2022

Dear Daniel Kamm:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2023.03.15 13:24:54 -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)*
K220122

Device Name
APEX 6

Indications for Use *(Describe)*
Intended for use for lesioning of neural tissue and for pain management. It is indicated for use in the peripheral nervous system. The APEX 6 is to be used with LCCS electrodes and cannulae and Conmed Thermogard Dispersive Electrodes.

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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510(k) Summary K220122

Date Prepared: March 10, 2023

SUBMITTED BY: RF Innovations, Inc
Middleton, MA 01940

CONTACT: William Rittman, Director.
RF Innovations, Inc
Middleton, MA 01949
781-640-1212

DEVICE NAME: APEX 6 Lesioning Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: II
Product Code: GXD

PREDICATE DEVICE: K111576
DEVICE NAME: NeuroTherm NT 2000 RF Lesioning Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: II
Product Code: GXD

Reference Devices: Compatible electrodes:
510(k) number: K191293
Trade/Device Name: LCCS RF Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
510(k) number: K152642
Trade/Device Name: LCCS Radiofrequency (RF) Electrode
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI

Compatible Dispersive Grounding Pad:
510(k) number: K140658
Trade/Device Name: Thermogard & Thermogard Plus ABC dispersive electrodes
Regulation Number: 21CFR878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

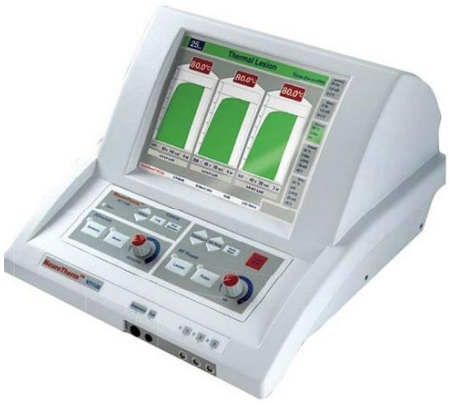
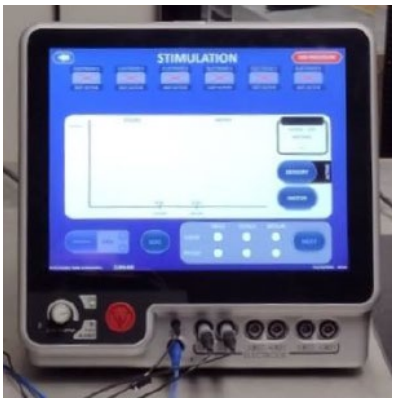
Product Code: GEI

DEVICE DESCRIPTION:

The RF Innovations APEX 6 is a desktop RF lesioning generator which is used for the lesioning of neural tissue. The APEX 6 is a multi-lesioning, 6 channel portable generator that can provide continuous or pulsed RF output at 460 kHz, and monopolar or dual electrode modes. The device includes sensory and motor stimulation functions to fine tune electrode placement for procedures. Based on performance testing the device is designed to connect to LCCS FDA cleared lesioning probes which are inserted into patients for lesioning of neural tissue during medical procedures. Device features include a touch screen monitor incorporating microprocessor and graphics display for user interface as well as self-diagnostics, calibration checks, and recordkeeping functions.

INDICATIONS FOR USE: Intended for use for lesioning of neural tissue and for pain management. It is indicated for use in the peripheral nervous system. The APEX 6 is to be used with LCCS electrodes and cannulae and Conmed Thermogard Dispersive Electrodes.

SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

	NeuroTherm NT 2000 Generator K111576	**RF Innovations APEX 6 Generator K220122**	**Discussion**
Indication for Use	The NT 2000 is intended for use for lesioning of neural tissue. The NT 2000 is indicated for use in the peripheral nervous system. The NT 2000 is to be used only, with FDA cleared NeuroTherm RF probes and Smith & Nephew SPINECATH and ACUTHERM catheters, catheters.	Intended for use for lesioning of neural tissue and for pain management. It is indicated for use in the peripheral nervous system. The APEX 6 is to be used with LCCS electrodes and cannulae and Conmed Thermogard Dispersive Electrodes.	SIMILAR
Appearance			SIMILAR
Touchscreen dimensions	12” diagonal LCD	15” diagonal LCD	SIMILAR

Number of Channels	4	6	Same max power delivered
RF Output Frequency	460 kHz	460 kHz	SAME
Maximum output power (100 ohm load)	50 watts	50 watts	SAME
Energy delivery during multi channel RF treatment	Independent sequential energy delivery	Independent sequential energy delivery	SAME
Power delivery modes	Continuous and pulsed	Continuous and pulsed	SAME
Power supply	AC Line	AC Line	SAME
Auto shutdown for power exceeding safe levels	Yes	Yes	SAME
Electrical safety/EMC	IEC 60601 compliant	Tested to ANSI/AAMI 60601-1:2005 + C1:2009 + A2:2010 + A1:2012, CAN/CSA-C22.2 & 60601-1:2014 AND ANSI/AAMI 60601-2-2:2017, CAN/CSA-C22.2 No. 60601-2-2:2019. AND IEC 60601-1-2:2014/ EN 60601-1-2:2015	Equivalent
RF energy delivery modes:			
Continuous thermal	YES	YES	SAME
Stimulation-sensory and motor	YES	YES	SAME
Pulsed RF	YES	YES	SAME
RF energy delivery channel types			
Monopolar	YES	YES	SAME
Bipolar*	Yes aka “dual”	Yes aka “dual”	SAME

* current between two monopolar electrodes

Any differences between the APEX 6 and the predicate 4-channel devices do not raise new issues of safety or effectiveness. The APEX 6 uses the same amount of energy output across 6 channels and delivers this energy sequentially as opposed to continuously. Therefore, the APEX 6 is substantially equivalent to the predicate device based upon the Indication for Use, technology, functional modes, hardware and software components, and performance.

PERFORMANCE TESTING

Bench - Bench testing supports that the APEX 6 performs as expected. Safety was tested in accordance with Standard for Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ANSI/AAMI 60601-1:2005 + Cl:2009 + A2:2010 + Al:2012, CAN/CSA-C22.2 No. 60601-1:2014 and the Standard for 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 ANSI/AAMI 60601-2-2:2017, CAN/CSA-C22.2 No. 60601-2-2:2019. EMC was tested in accordance with IEC 60601-1-2:2014/ EN 60601-1-2:2015/IEC 60601-2-2.

Test	Test Method Summary	Results
Lesion size	Purpose was to document the maximum linear dimensions in all three planes as well as the volume for the affected tissue region and compare them to the predicate device for minimal, typical, and maximum energy delivery	Analysis: All affected area differences were less than 1 mm. Minor errors can introduced by: • Measuring small diameters with fuzzy borders can increase the measurement error. • For volume, a 10% error in the linear dimensions will result in a 33% error in volume. Therefore this study confirms that the Apex 6 and the predicate device are substantially equivalent in regards to affected tissue size.
Comparison of treatment times between NeuroTherm NT 2000 and Apex 6	The purpose of this protocol is to measure and compare the time to ramp up to set temperature of the Apex 6 and the predicate device under worse case conditions to evaluate the efficiency of energy delivery and measure treatment times.	Results demonstrated that the APEX 6 was substantially equivalent in terms of treatment times compared to the predicate device.
Design Validation Review	A documented review of device acceptance criteria was performed to confirm compliance with the following plans: • Requirement Specification • Requirements, Design and Verification Traceability Matrix • Embedded Software Requirement Specification • GUI Software Requirement Specification • Embedded Software Validation Plan • GUI Software Validation Plan • Instructions for Use	The finished unit design review verified that all documented device requirements were met.
Every unit functional test	Every unit manufactured is subjected to a full functional test regimen and the results are recorded in the Device History Record: Voltage checks Program and Impedance Testing Software testing Main GUI	Each unit must pass all tests prior to shipment.

Test	Test Method Summary	Results
	Final testing: Impedance/Temperature measurement Electrical safety testing	

Software - Software testing supports that the APEX 6 performs as expected. Validation was performed to the FDA Moderate Level of Concern per the FDA software guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*

CLINICAL TESTING Not required.

CONCLUSION

The APEX 6 is similar to or the same as the predicate device as follows:

- Technology
- Intended use/Indication for Use
- Technical specifications, or ranges of technical specifications
- Functional modes compared to 4-channel devices

The fundamental technological characteristics of the APEX 6 are substantially equivalent to the predicate device based upon the Indication for Use, technology, functional modes, hardware and software components, and performance. Therefore, the APEX 6 is substantially equivalent to the predicate device.