October 21, 2020

Jim Chapman
Manager, Regulatory Affairs
5050 Nathan Lane
Plymouth, Minnesota 55442

Re: K201610
Trade/Device Name: IonicRF™ Generator
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD
Dated: September 16, 2020
Received: September 21, 2020

Dear Jim Chapman:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201610

Device Name
IonicRF™ Generator

Indications for Use *(Describe)*
The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is indicated as an aid in the management of pain in the nervous system. Examples include, facet denervation, trigeminal rhizotomy, and related functional neurosurgical 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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510(K) SUMMARY

510(k) Number: **K201610**

510(k) Type: Traditional 510(k)

Manufacturer Name & Address
Abbott Medical
5050 Nathan Lane North
Plymouth, Minnesota, 55442
USA

Contact Person
Jim Chapman
Manager, Regulatory Affairs
972-526-4624
jim.chapman@abbott.com

Device Information

Trade Name IonicRF™ Generator

Common Name Radiofrequency lesion generator

Class II

Classification Name 882.4400 Generator, Lesion, Radiofrequency

Product Code GXD

Predicate Device NeuroTherm NT2000 Lesioning Generator (K111576)

Device Description

The Abbott IonicRF™ Generator is a desktop radiofrequency (RF) lesioning generator, which is intended for lesioning of neural tissue in the peripheral nervous system as an aid in the management of pain.

The generator is portable and can be placed on a level surface using the countertop stand or mounted to a compatible roll stand using the optional pole mount.

The IonicRF™ Generator is a multi-lesioning, 4 channel portable generator that can provide continuous or pulsed RF output at 460 KHz, monopolar or dual electrode modes, and a Simplicity™ mode for large lesion creation. The generator includes sensory and motor stimulation functions to fine-tune electrode placement before procedures are performed. The generator is also designed to be compatible with all existing Abbott electrodes and cannulas.

Device features include a touch screen monitor incorporating microprocessor and graphics display for user interface, and recordkeeping functions. The user interface controls all functions of the generator. The generator incudes a dial on the front for control of stimulation level during stimulation and motor testing. The IonicRF™ Generator can be set on a flat surface or mounted on a pole with the accessory pole mount bracket.

The IonicRF™ Generator can be used with previously cleared Abbott RF Electrodes (K011387, K111576), and Cannula/Introducers (K042375, K000073) used with the predicate device.

Indications for Use The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is indicated as an aid in the management of pain in the nervous system. Examples include, facet denervation, trigeminal rhizotomy, and related functional neurosurgical procedures.

Intended Use The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is intended for lesioning of neural tissue in the nervous system as an aid in the management of pain.

Comparison of Technological Characteristics with the Predicate Device

The predicate device is the Abbott NeuroTherm™ NT2000 generator. The intended use of the IonicRF™ Generator and the predicate device is the same. Both are indicated for the lesioning of neural tissue.
Based on comparison of intended use and technical characteristics, the IonicRF™ Generator is similar to the legally marketed predicates. Hardware and software verification and validation demonstrated the IonicRF Generator meets performance specifications. Any differences between the IonicRF™ Generator and predicate devices do not raise new types of questions of safety and effectiveness. Therefore, the IonicRF™ Generator is substantially equivalent to the predicate device.

Substantial Equivalence Table

Parameter	Subject Device Abbott Medical IonicRF™ Generator	Primary Predicate Abbott Medical (NeuroTherm™) NT2000 Generator	Equivalency Discussion
510(k)	TBD	K111576	Not Applicable
Product Code	GXD	GXD	Equivalent to predicate
Indication for Use	The IonicRF™ Generator, in combination with approved compatible electrodes and cannulae, is indicated as an aid in the management of pain in the nervous system. Examples include, facet denervation, trigeminal rhizotomy, and related functional neurosurgical procedures.	The NT2000 is intended for use for lesioning of neural tissue. The NT2000 is indicated for use in the peripheral nervous system. The NT2000 is to be used only with FDA cleared NeuroTherm RF probes and Smith & Nephew SPINCATH and ACUTHERM catheters	The verbiage is different, but the differences do not raise new issues of safety and effectiveness since the IonicRF Generator is used in the same manner as the predicate for the same procedures using the same accessories. Neural tissue lesioning is used by physicians to aid in the management of pain
Modes of Operation	Pulsed and continuous lesioning. Sensory and motor stimulation.	Pulsed and continuous lesioning. Sensory and motor stimulation.	Equivalent to predicate
Generator Dimensions	35.3 cm H x 32.8 cm W x 28.6 cm D	32.0 cm H x 37.0 cm W x 43.0 cm D	The IonicRF™ Generator is similar in height and width to the predicate. The proposed generator is thinner and weighs 10 lbs less than the predicate
Maximum Weight	7.3 kg (16.0 lb)	12 kg (26.4 lb)	
Display	30.5 cm (12") diagonal, 1024x768 pixels, Capacitive Touch Screen	12” 1366x768 Touch Screen	The IonicRF has the same size touch screen
Number of electrode Connections	4	4	Equivalent to predicate
Monopolar/Bipolar	Both	Both	Equivalent to predicate
Output Energy	50 watts	50 watts	Equivalent to predicate
Maximum Current	700 mA	625 mA	Similar. This is a function of the power management. In addition, 700mA is the limit specified in IEC 60601-2-2
Measuring Frequency	460 kHz ± 3%	460 kHz ± 3%	Equivalent to predicate
Able to Mount on a Roll Stand	Yes	No	Added feature of the IonicRF Generator
Uses all of Abbott’s Cannulas and Electrodes	Yes	Yes	Equivalent to predicate
Printer Connection	No	Yes	Removed feature not frequently used
USB for Flash Drive	Yes (2)	Yes (1)	Similar, IonicRF™ Generator has 2
Ability to Store User Profiles and Treatment Profiles	Yes	Yes	Equivalent to predicate
Ability to be Upgraded	Yes	Yes	
Ability to Generate Treatment Reports	Yes	Yes	
Probe Recognition	Yes	Yes	

Non-Clinical Testing Summary

Non-clinical testing included assessment of the physical properties of the IonicRF™ Generator to ensure the IonicRF™ Generator met all of the performance requirements and specifications. The test results demonstrated the suitability of the IonicRF™ Generator for its intended use and supported the substantial equivalence to the predicate device. Risk management in accordance with ISO 14971 was used throughout the non-clinical verification activities. Testing included the following:

Test	Test Summary	Results
EMC and Electrical Product Safety Testing	The IonicRF Generator together with approved accessories were tested in accordance with IEC 60601-1 and IEC 60601-1-2.	The IonicRF™ Generator met all relevant requirements confirming compliance with IEC 61601-1 and IEC 60601-1-2.
Hardware Performance Testing	Testing was performed to demonstrate the hardware will function as intended through the expected lifetime of the device.	The hardware testing met all performance requirements.
Comparative Lesion Testing	Comparative lesion testing was performed to support substantial equivalence of the IonicRF™ Generator to the predicate.	The generator met all performance requirements and supports the substantial equivalence to the predicate device.
Software Verification and Validation	Software verification and validation testing was performed to ensure the generator met all relevant requirements.	Testing demonstrated the IonicRF™ Generator met all software requirements.
Usability	Testing was performed to verify and validate the usability of the IonicRF™ Generator.	The generator met all usability requirements. Results support the substantial equivalence to the predicate device.

A biocompatibility assessment of the device was performed and established, based on the materials of construction that the IonicRF™ Generator is biocompatible.

Clinical Testing

Based on substantial equivalence to the predicate device and results of testing, clinical studies were not required to establish substantial equivalence of the IonicRF™ Generator.

Statement of Equivalence

Based on comparison of intended use and technical characteristics, the IonicRF™ Generator is similar to the legally marketed predicate. Hardware and software verification and validation demonstrated the IonicRF™ Generator met all performance specifications. Any differences between the IonicRF™ Generator and the predicate device do not raise new types of questions of safety and effectiveness. Therefore, the IonicRF™ Generator is substantially equivalent to the predicate device.