Abbott Medical
Jordan Hanson
Project Manager, Regulatory Affairs
5050 Nathan Lane
Plymouth, Minnesota 55442

Re: K203293
Trade/Device Name: Abbott Medical Grounding Pad, model RF-DGP-IS
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency Lesion Generator
Regulatory Class: Class II
Product Code: GXD
Dated: December 21, 2021
Received: December 22, 2021

Dear Jordan Hanson:

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 Adam Pierce
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)*

K203293

Device Name
Abbott Medical Grounding Pad

Indications for Use *(Describe)*
This disposable electrosurgical return electrode with conductive adhesive gel is used in monopolar electrosurgical procedures for adult patients.

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.

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510(k) Summary

510(k) Number:	K203293
510(k) Type:	Traditional 510(k)
Date Prepared:	21 December 2021
Manufacturer Name & Address:	Abbott Medical 5050 Nathan Lane North Plymouth, Minnesota, 55442 USA
Contact Person:	Jordan Hanson Project Manager, Regulatory Affairs (972) 309-2113 jordan.hanson@abbott.com

Device Information

Trade Name:	Abbott Medical Grounding Pad (Model: RF-DGP-IS)
Common Name:	Grounding Pad
Class:	II
Classification Name:	882.4400 Radiofrequency Lesion Generator
Product Code:	GXD
Predicate Device:	Cathay Disposable Neutral Electrode (Model: GP202D-AC)
Predicate 510(k):	K130027
Device Description:	The Abbott Medical Grounding Pad is a dispersive electrode that is designed for use in monopolar electrosurgical procedures in adult patients. It is a single-use, non-sterile and disposable device. The Abbott Medical Grounding Pad is compatible with the IonicRF™ Generator and provides a path for radiofrequency (RF) energy produced at an RF electrode to return to the generator. The Abbott Medical Grounding Pad consists of a grounding pad component (also called a neutral electrode, dispersive electrode or return electrode) and an attached cable. The grounding pad component includes a conductive aluminum foil layer which acts as the neutral electrode that connects back to the generator. The aluminum foil layer is covered with a conductive hydrogel adhesive which is covered with a protective liner while it is packaged.
Indications for Use:	This disposable electrosurgical return electrode with conductive adhesive gel is used in monopolar electrosurgical procedures for adult patients.

Comparison of Technological Characteristics with the Predicate Device

The predicate device is the Cathay Disposable Neutral Electrode (cleared in K130027). The intended use of the Abbott Medical Grounding Pad and predicate device are the same. Both are electrosurgical return electrodes used in electrosurgical procedures in adult patients.

Based on comparison of intended use and technical characteristics, the Abbott Medical Grounding Pad is similar to the legally marketed predicate device. The only design difference is the use of the different adhesive liner that covers the adhesive while the grounding pad is packaged and is removed before use. A biocompatibility assessment and biocompatibility testing of the patient skin-contacting materials confirm the biological safety of the Abbott Medical Grounding Pad. Bench and electrical testing demonstrate that the grounding pad meets its performance specifications. Any differences between the Abbott Medical Grounding Pad and the predicate device do not raise new questions of the safety and efficacy. Therefore, the Abbott Medical Grounding Pad is substantially equivalent to the predicate device.

Substantial Equivalence Table

Description	**Subject Device** Abbott Medical Grounding Pad (model: RF-DGP-IS) 510(k): K203293	**Predicate Device** Cathay Disposable Neutral Electrode 510(k): K130027	**Discussion**
General Characteristics			
Common Name	Grounding Pad	Grounding Pad	Same as predicate
Class	II	II	
Classification Name	21 CFR 882.4400: Radiofrequency Lesion Generator	21 CFR 878.4400: Electrosurgical cutting and coagulation devices and accessories	The Abbott Medical Grounding Pad is compatible only with the IonicRF Generator, therefore it is using the same product code to align with the system it is intended to be used with.
Product Code	GXD	GEI	
Indications for Use	This disposable electrosurgical return electrode with conductive adhesive gel is used in monopolar electrosurgical procedures for adult patients	This disposable neutral electrode for adult patients with conductive adhesive gel is used as neutral reference during electrosurgical procedures	The wording of the indications has updated slightly to align with verbiage across Abbott's RF system instructions for use. The Abbott Medical Grounding Pad is indicated for monopolar electrosurgical procedures, which is a subset of the indications for the predicate device.
Prescription or OTC	Prescription	Prescription	Same as predicate
Technical Specifications/Characteristics			
Type of Conductor	Conductive	Conductive	Same as predicate
Conductive Material	Same	Same	
Sterile	No	No	
Single Use	Yes	Yes	

Description	**Subject Device** Abbott Medical Grounding Pad (model: RF-DGP-IS) 510(k): K203293	**Predicate Device** Cathay Disposable Neutral Electrode 510(k): K130027	Discussion
Electrode Conductive Surface Area	127.8 cm^2	**Configuration 1:** 121 cm^2 **Configuration 2:** 127.8 cm^2	Same as predicate configuration 2
Overall Dimensions	203 (±2mm) x 105 (±2mm)	202mm x 107mm	Similar to predicate
Conductive Adhesive Material	Conductive adhesive: Hydrogel	Conductive adhesive: Hydrogel	Similar to predicate
Adhesive Liner	Single-sided silicone coated PET (thermoplastic polyester), clear	Double-sided silicone coated release paper, white	Similar to predicate

Non-clinical Testing Summary

The Abbott Medical Grounding Pad design is identical to the predicate device with the exception of the adhesive liner material. Non-clinical testing was performed to confirm that the physical, electrical and biological properties of the Abbott Medical Grounding Pad meet the performance requirements and specifications. Due to the design similarities, testing using the predicate device is leveraged to support requirements related to identical aspects of the predicate and subject devices. The passing test results demonstrated that the Abbott Medical Grounding Pad meets its product requirements and that no new questions of safety and effectiveness are raised. Testing included the following:

Test	Leveraged or New Testing	Test Summary	Results
Biocompatibility	New The patient skin contacting hydrogel material with PET liner was evaluated to evaluate the biocompatibility impact of the change in adhesive liner material.	The hydrogel material with PET liner was evaluated per ISO 10993-1. Testing included cytotoxicity, sensitization and irritation testing.	PASS The hydrogel material with PET liner passed all testing for cytotoxicity, sensitization and irritation. Therefore, the difference in the adhesive liner material does not raise new questions of safety and effectiveness.
EMC and Electrical Product Safety Testing	Leveraged The design of the subject and predicate devices is identical for all electrical	The Cathay Disposable Neutral Electrodes (predicate device) were tested in accordance with IEC 60601-1, IEC	PASS The devices met all relevant requirements confirming compliance

Test	Leveraged or New Testing	Test Summary	Results
	aspects, therefore testing on the predicate device applies to the Abbott Medical Grounding Pad.	60601-1-2 and IEC 60601-2-2.	with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2.
Grounding Pad Cable Tensile Strength	New The tensile strength of the cable attachment to the grounding pad was evaluated after aging to ensure it meets the product requirements (≥20N).	Tensile strength of the cable attachment to the grounding pad was evaluated to ensure it meets the product requirements (≥20N).	PASS The devices met the tensile strength requirements of ≥20N.
Shelf Life and Operating Environment Testing	New Aging testing was performed to confirm that the device meets its requirements at the end of shelf-life. Additionally, operating environment testing was performed with the generator system to confirm functionality in the operating conditions. The shelf life and operating environment of the Abbott Medical Grounding Pad are within the ranges for the predicate device.	Testing was performed to confirm that the devices met the performance specifications while within the range of the operating environment and at the end of the 2-year shelf life.	PASS The devices met all requirements while within the range of the operating environment and at the end of the 2-year shelf life.
Usability	New and Leveraged The use of the Abbott Medical Grounding Pad falls within the range of use for the predicate device and the change to the adhesive liner does not impact usability.	Testing was performed to confirm the usability of the grounding pad as a standalone device and as part of a RF generator system.	PASS The devices met all relevant requirements and confirm that the device is usable when operated as intended.

Clinical Testing

Based on substantial equivalence to the predicate device, clinical studies were not required to establish the safety or effectiveness of the Abbott Medical Grounding Pad.

Statement of Equivalence

Based on comparison of intended use and technical characteristics, the Abbott Medical Grounding Pad is similar to the Cathay Disposable Neutral Electrode. The results of testing confirm that the subject device meet the prescribed product requirements and differences in the subject and predicate device do not raise new questions of safety and effectiveness. Therefore, the Abbott Medical Grounding Pad is substantially equivalent to the predicate device.