



August 7, 2025

Boston Scientific Neuromodulation Corporation
Alex Hoang
Principal Regulatory Affairs Specialist
25155 Rye Canyon Loop
Valencia, California 91355

Re: K251247

Trade/Device Name: GX1 Radiofrequency Generator Kit (RFG-X1-120V); GX1 Radiofrequency Generator Kit (RFG-X1-220V); GX1 Radiofrequency Generator Kit (RFG-X1-240V); GX1 System Release Rest of World (GX1-SYS-ROW); GX1 Radiofrequency Generator (51779845-01); GX1 Radiofrequency Generator (51779845-02); GX1 Radiofrequency Generator (51779845-03)

Regulation Number: 21 CFR 882.4400

Regulation Name: Radiofrequency Lesion Generator

Regulatory Class: Class II

Product Code: GXD

Dated: April 22, 2025

Received: July 7, 2025

Dear Alex Hoang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

Yen-chih Lin - Digitally signed by Yen-chih
Lin -S
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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

Indications for Use

510(k) Number (if known)

K251247

Device Name

GX1 Radiofrequency Generator Kit (RFG-X1-120V); GX1 Radiofrequency Generator Kit (RFG-X1-220V); GX1 Radiofrequency Generator Kit (RFG-X1-240V); GX1 System Release Rest of World (GX1-SYS-ROW); GX1 Radiofrequency Generator (51779845-01); GX1 Radiofrequency Generator (51779845-02); GX1 Radiofrequency Generator (51779845-03).

Indications for Use (Describe)

The Boston Scientific RFG-X1 (GX1) Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. The Boston Scientific GX1 Radiofrequency Generator is used with separately approved Boston Scientific Radiofrequency Probes

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

A. Device Information:

Category	Comments
Sponsor:	Boston Scientific Neuromodulation Corporation 25155 Rye Canyon Loop Valencia, CA 92355
Correspondent Contact Information:	Alexander Hoang Principal Regulatory Affairs Specialist
Registration Number	3006630150
Device Common Name:	Radiofrequency Ablation Generator
Device Regulation & Name:	Radiofrequency Lesion Generator (21 CFR 882.4400)
Classification & Product Code: 510(k) Number:	Class II, GXD K251247
Device Proprietary Name:	GX1™ Radiofrequency Generator Kit (RFG-X1-120V) GX1™ Radiofrequency Generator Kit (RFG-X1-220V) GX1™ Radiofrequency Generator Kit (RFG-X1-240V) GX1™ System Release Rest of World(GX1-SYS-ROW) GX1™ Radiofrequency Generator (51779845-01) GX1™ Radiofrequency Generator (51779845-02) GX1™ Radiofrequency Generator (51779845-03)

Predicate Device Information	
Predicate Device:	G4 Radiofrequency Ablation Generator
Predicate Device Manufacturer:	Boston Scientific Neuromodulation Corporation
Predicate Device Common Name:	Radiofrequency Ablation Generator
Predicate Device Premarket Notification #	K082051
Predicate Device Regulation & Name	Radiofrequency Lesion Generator (21 CFR 882.4400)
Predicate Device Classification & Product Code:	Class II GXD

B. Date Summary Prepared

August 4, 2025

C. Description of Device

The Boston Scientific GX1 Radiofrequency (RF) Generator is a 50W RF lesion generator that supplies electrical power to associated RF Probes. During RF energy delivery, power is continuously monitored and controlled, based on temperature and impedance measurements at the treatment site, to ensure proper operation. The GX1 Generator is a product line extension of the Boston Scientific G4 Radiofrequency Generator which is FDA approved under 510(k) K082051.

The GX1 Generator is a small, portable unit (14.3” W x 10.8” H x 12.5” D, 24lbs) that can accommodate line Voltage between 100 and 240 Volts. The GX1 Generator has advanced functionality and a Graphical User Interface (UI) equivalent to the Boston Scientific RF Generator, its predicate device.

D. Indications for Use

The Boston Scientific RFG-X1 (GX1) Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. The Boston Scientific GX1 Radiofrequency Generator is used with separately approved Boston Scientific Radiofrequency Probes

E. Comparison of the Technological Characteristics

Radiofrequency ablation is the technological principle for both the subject and predicate devices. Both lesion generators supply electrical power to associated RF Probes. During RF energy delivery, power is continuously monitored and controlled, based on temperature and impedance measurements at the treatment site, to ensure proper operation. Both generators have a Graphical User Interface (GUI) that allows the user to control its advanced functionalities. Both generators have a stimulator that enables the user to deliver stimulating current in either Current-controlled or Voltage Controlled mode, according to the physician’s preference. The GX1 Generator is substantially equivalent to the existing commercial G4 Generator. The GX1 Generator has the same intended use, scientific technology, design, materials, cleaning and sterilization method, and packaging materials as the applicable predicate device.

Company	Boston Scientific	Boston Scientific	Comparison
Device	Application Device: GX1 RF Generator	Predicate Device: G4 RF Generator	
510(k)	K251247	K082051	--
FDA Classification/ Product Code	II GXD, 882.4400	II GXD, 882.4400	Equivalent
Intended Use	The generator is intended to be used as a power source to deliver RF energy via compatible RF Electrodes and Cannulas.		Equivalent

Company	Boston Scientific	Boston Scientific	Comparison
Device	Application Device: GX1 RF Generator	Predicate Device: G4 RF Generator	
Indications for Use	The GX1 Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. The GX1 Radiofrequency Generator is used with separately approved Boston Scientific Radiofrequency Probes.	The G4 Radiofrequency Generator is indicated for use in procedures to create radiofrequency lesions for the treatment of pain, or for lesioning nerve tissue for functional neurosurgical procedures. The G4 Radiofrequency Generator is used with separately approved Boston Scientific Radiofrequency Probes.	Equivalent
Electrical Supply			
Voltage Specifications	100/120/220/240 VAC	100/120/220/240 VAC	Equivalent
Max Input Voltage	260 VAC	260 VAC	Equivalent
Max Input Power	480 VA	480 VA	Equivalent
Frequency	50/60 Hz	50/60 Hz	Equivalent
Environmental Operating Range			
Temperature	15°C–40°C	15°C–40°C	Equivalent
Humidity	15–80% (non-cond.)	15–80% (non-cond.)	Equivalent
Pressure	620–1060 hPa	500–1060 hPa	Different
Transport/Storage Range			
Temperature	-29°C–60°C	-29°C–60°C	Equivalent
Humidity	15–80% (non-cond.)	15–80% (non-cond.)	Equivalent
Impedance Monitor			
Range	0–3000 ohms digital	0–3000 ohms digital	Equivalent
Resolution	1 ohm (<999), 10 ohm (1–3K)	1 ohm (<999), 10 ohm (1–3K)	Equivalent
Contact Quality Monitoring (CQM)	Yes	no	Different
Stimulator Output			
Rate	2, 5, 50, 75, 100, 150, 180, 200 Hz	2, 5, 50, 75, 100, 150, 180, 200 Hz	Equivalent
Duration	0.1, 0.5, 1, 2, 3 ms	0.1, 0.5, 1, 2, 3 ms	Equivalent
Voltage-controlled mode	0–5 V	0–5 V	Equivalent
Current-controlled mode	0–10 mA	0–10 mA	Equivalent
Parameters			
Timing (Selectable)	30–1800 sec	30–1800 sec	Equivalent
Resolution	1 second	1 second	Equivalent
Voltage Range	0–70 V	0–70 V	Equivalent
Voltage Resolution	1 volt	1 volt	Equivalent
Current Range	0–700 mA	0–700 mA	Equivalent
Current Resolution	1 mA	1 mA	Equivalent
Power Output	0–50 W	0–50 W	Equivalent
Power Resolution	0.1 W (<1 W), 1 W (≥1 W)	0.1 W (<1 W), 1 W (≥1 W)	Equivalent
Frequency	480 kHz ±3%	480 kHz ±3%	Equivalent

Company	Boston Scientific	Boston Scientific	Comparison
Device	Application Device: GX1 RF Generator	Predicate Device: G4 RF Generator	
Pulsed Mode			
Repetition Rate	1–10 Hz	1–10 Hz	Equivalent
Duration	2-50 ms	2-50 ms	Equivalent
Temperature Monitor			
Range	0–110 °C	0–110 °C	Equivalent
Resolution	1 °C	1 °C	Equivalent
Temperature Control			
Range	37–90 °C	37–90 °C	Equivalent
Resolution	1 °C	1 °C	Equivalent

F. Summary of Supporting Data

The following performance data were provided in support of the substantial equivalence determination.

Electromagnetic Compatibility and Electrical Safety Testing:

The GX1 RF Ablation System was evaluated for compliance with the following standards and was found to be complying:

- IEC 60601-1; Medical electrical equipment; Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2; Medical electrical equipment; Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility
- IEC 60601-2-2; 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

Tests	Test Method Summary	Results
High Frequency Surgical Equipment and Accessories – Safety Testing	Type testing/conformity testing per IEC 60601-2-2:2017/AMD1:2023, Edition 6.1 – 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.	Pass
Medical Electrical Equipment – Safety Testing	Type testing/conformity testing per IEC 60601-1 Ed. 3.2: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
Electromagnetic Compatibility	Type testing/conformity testing per IEC 60601-1-2 Ed. 4.1: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential	Pass

	performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	
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Performance Testing

A range of design verification testing was conducted to confirm the subject devices perform as intended and are safe and effective for their intended use. Results of performance testing are summarized below.

GX1 RF Ablation System Test	Test Summary	Results
Design Verification Testing	<ul style="list-style-type: none"> - RF Power vs Load Curve - RF Output Voltage Measurement - RF Output Current Measurement - RF Output Impedance Measurement - RF Ramp Rate Control - Stimulation Output Voltage - Stimulation Output Current - Ablation Temperature Measurement - Contact Quality Measurement 	Pass
Packaging Testing	Conform to ASTM D4169 Standard Practice for performance testing of shipping containers and systems	Pass
Mechanical Testing	<ul style="list-style-type: none"> - Tamper Resistant screws - Cleaning Test - Drop Test - Impact Test - Flammability - Overbalance - Durable Labels - Ingress Protection - Operational conditions (Temperature, Pressure and Humidity) 	Pass
Lesion Size Comparison Test	Compare lesions size in homogenous tissue using G4 (Predicate) vs GX1 System	Pass
Dimension and Weight	Meet dimensional and weight specifications per product specification	Pass
Software Verification	<ul style="list-style-type: none"> - User Workflow and Information Display - Touch Screen - Error Display - Report/Diagnose Logging - Security - Language Translation - Therapy Template 	Pass

G. Discussion of Performance Testing

Electrical safety and Electromagnetic compatibility (EMC)

Electrical Testing

Electrical verification testing of relevant components of the GX1 RFG was conducted and demonstrated compliance with current electrical safety standards IEC 60601-1 and IEC 60601-2-2.

Electromagnetic Compatibility (EMC)

EMC testing of relevant components of the GX1 RFG was conducted and demonstrated compliance with current standard IEC 60601-1-2.

Software

Software verification and validation testing were conducted and demonstrated compliance with all software requirements.

Performance Testing - Bench

Non-clinical bench testing included GX1 system verification and validation, packaging verification, and usability studies. Design Verification testing confirmed that all design outputs met the design input requirements. Design Validation testing confirmed that the GX1 RFG conforms to the user needs and intended uses.

H. Conclusion

The results of the EMC, Software, and Performance tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing. All testing was completed with acceptable results.

Based on the indications for use, technological characteristics, and results of verification and validation testing, the GX1 Generator has been shown to be appropriate for its intended use and is substantially equivalent to its predicate (K082051).