May 15, 2025

Stryker Instruments
Dayana Manganese
Staff Specialist, Regulatory Affairs
1941 Stryker Way
Portage, Michigan 49002

Re: K250213
Trade/Device Name: OptaBlate BVN Intraosseous Nerve Ablation System (10mm Probe Single Kit); OptaBlate BVN Intraosseous Nerve Ablation System (10mm Probe Dual Kit)
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: January 24, 2025
Received: January 24, 2025

Dear Dayana Manganese:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.05.15 16:23:56 -04'00'

Adam 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250213

Device Name

OptaBlate BVN Intraosseous Nerve Ablation System (10mm Probe Single Kit);
OptaBlate BVN Intraosseous Nerve Ablation System (10mm Probe Dual Kit)

Indications for Use *(Describe)*

The Stryker OptaBlate BVN Intraosseous Nerve Ablation System is intended for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

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

Submitter Information

510(k) Owner/Submitter:	Stryker Instruments 1941 Stryker Way Portage, MI 49002 USA
Contact Person:	Dayana Manganese Staff Regulatory Affairs Specialist
Registration Number:	3015967359
Date Summary Prepared:	5/12/2025

Device Name

Trade Name(s):	OptaBlate BVN Intraosseous Nerve Ablation System
Regulation	Radiofrequency lesion probe (21 CFR 882.4725)
Device Class:	Class 2
Product Code:	GXI

Predicate Device

Predicate Device	
Device Name	Intracept Intraosseous Nerve Ablation System (RF Probe), Intracept Intraosseous Nerve Ablation System (Access Instruments), Relievant RF Generator
510(k) Number	K190504

Device Description

The subject device Stryker Optablate® BVN Intraosseous Nerve Ablation System is a bipolar, high frequency electrosurgical system comprising the BVN probe, Microinfuser, syringe, introducer handpiece, introducer conduit, 10 G access cannula with diamond tip stylet, and 10 G bevel tip stylet.

The subject device is intended to be used in conjunction with the existing Optablate radiofrequency (RF) generator (K221074), MultiGen2 Splitter Cable (K170242), and Optablate Microinfuser (K221074) to produce lesions by the direct application of radiofrequency currents for the relief of chronic low back pain. The subject generator applies temperature-controlled, radiofrequency (RF) energy into the probe. During lesion creation, targeted tissue is exposed to RF energy using an active probe inserted into a conduit that is within an access cannula. The application of RF energy causes a thermal reaction at the targeted tissue site to ablate the basivertebral nerve. It is indicated for the L3 through S1 vertebrae.

When used, the subject OptaBlate BVN probes are connected to the splitter cable, which is connected to the generator, to deliver RF energy to the target tissue. The Optablate Microinfuser is connected to the probe to deliver a small amount of saline to the ablation site. The saline exits the probe between the emitters and helps ensure there is good electrical connection between the emitters and the tissue. The quality of the connection is measured in units called impedance. Impedance goes up if the connection is poor. If the impedance goes to high, the generator will trigger an error and stop the ablation. The Microinfuser slowly introduces saline to prevent impedance rises.

Indications for Use

The Stryker OptaBlate BVN Intraosseous Nerve Ablation System is intended for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

Substantial Equivalence Comparison

The predicate device has been identified as the Intracept Intraosseous Nerve Ablation System Relievant Medsystems RF Generator (RFG) (K190504). Both subject and predicate devices share the same intended use, and similar indications for use and technological characteristics. Results of verification and validation demonstrate that these differences do not introduce new questions of safety and effectiveness. The subject devices are at least as safe and effective as the predicate device.

Intended Use Comparison

	Subject	**Predicate**
	Stryker OptaBlate BVN Intraosseous Nerve Ablation System	**Intracept Intraosseous Nerve Ablation System Relievant Medsystems RF Generator (RFG) (K190504)**
Product Code	GXI	GXI
Indications for Use	The Stryker OptaBlate BVN Intraosseous Nerve Ablation System is intended for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).	The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change). The Relievant RFG is intended to be used with RF probes FDA cleared as part of the Relievant Intracept Intraosseous Nerve

	Subject	**Predicate**
	Stryker OptaBlate BVN Intraosseous Nerve Ablation System	**Intracept Intraosseous Nerve Ablation System Relievant Medsystems RF Generator (RFG) (K190504)**
		Ablation System for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).
Single Use?	Single Use	Single Use
Anatomical Site	Basivertebral nerves of the L3 through S1 vertebrae.	Basivertebral nerves of the L3 through S1 vertebrae
Method of Access	Percutaneous	Percutaneous

Technological Characteristics Comparison

	Subject	**Predicate**
	Stryker OptaBlate BVN Intraosseous Nerve Ablation System	**Intracept Intraosseous Nerve Ablation System Relievant Medsystems RF Generator (RFG) (K190504)**
Energy Type	Radiofrequency Energy	Radiofrequency Energy
Principle of Operation	Operator-controlled; RF delivered from compatible generator.	Operator-controlled; RF delivered from compatible generator.
Mechanism of Action	Cellular necrosis through thermal coagulation.	Cellular necrosis through thermal coagulation.
Compatible RF Generator	OptaBlate RF Generator (K221074)	Stockert Neuro N50 Generator (K070336) Relievant Medsystems RF Generator (K171143)
Temperature	95°C	85°C
Temperature Ramp	~0.27°/second	1°/second
RF Duration	7 minutes	15 minutes
Saline Infusion	6 ml/hour	None
Active Electrode Length	10mm	10mm
Active Electrode Material	Stainless Steel with Gold Plating	Stainless Steel
Electrode Insulation	Polyether Block Amide (Pebax)	Polyether Block Amide (Pebax)

	Subject	Predicate
	Stryker OptaBlate BVN Intraosseous Nerve Ablation System	**Intracept Intraosseous Nerve Ablation System** **Relievant Medsystems RF Generator (RFG) (K190504)**
Material		
Electrode Diameter	1.75mm	2.0mm
Components		
Cannula	10G Access Cannula with Diamond Point Stylet	8G Access Cannula with Diamond Point Stylet
Stylet	10G Bevel Stylet	8G Bevel Stylet
Curved Access Introducer	Introducer Handpiece	Introducer
Access Conduit	10G Introducer Conduit Peek	10G Introducer Conduit Peek
Saline Infusion	Microinfuser	Not used.

Summary of Non-Clinical Testing

A suite of performance testing, including Sterilization, Biocompatibility, Electrical Safety and EMC Testing, was conducted to demonstrate substantial equivalence with the predicate device. The following performance data were provided in support of the substantial equivalence determination.

Sterilization

Sterilization of the Stryker OptaBlate BVN Kits is completed using Ethylene Oxide. Sterilization validation was completed with conformance with ISO 11135:2014 and ISO 10993-7:2008/Amd 1:2019
Sterilization of the Microinfuser with Syringe is completed using Radiation. Sterilization validation was completed with conformance with ISO 11137-1:2006, ISO 11137-2:2013 and ISO 11137-3:2017.

Biocompatibility

Patient contact materials are classified as tissue/bone/dentin < 24hours and tested for compliance with applicable ISO 10993 standards.
This table summarizes the biocompatibility testing done and the results.

Stryker OptaBlate BVN Intraosseous Nerve Ablation System: Probe Tests	**Test Method Summary**	**Results**
Cytotoxicity – MEM Elution	Standards: ISO 10993-5:2009 ISO 10993- 12:2021 Acceptance Criteria: Test article to be considered non-cytotoxic.	Pass
Cytotoxicity – MEM Elution (Aged)	Standards: ISO 10993-5:2009 ISO 10993- 12:2021 Acceptance Criteria: Test article to be considered non-cytotoxic.	Pass
Cytotoxicity- MTT	Standards: ISO 10993-5:2009 ISO 10993- 12:2021 Acceptance Criteria: Test article to be considered non-cytotoxic.	Pass

Stryker OptaBlate BVN Intraosseous Nerve Ablation System: Probe Tests	**Test Method Summary**	**Results**
Irritation – Intracutaneous Reactivity	Standards: ISO 10993-23:2021 ISO 10993-12:2021 Acceptance Criteria: Difference between the test article and control is less than or equal to 1.0	Pass
Acute Systemic Toxicity	Standards: ISO 10993-11:2017 ISO 10993-12:2021 Acceptance Criteria: Test article shows no greater biological reaction than animals treated with control	Pass
Sensitization – Guinea Pig Maximization	Standards: ISO 10993-10:2010 ISO 10993-12:2021 Acceptance Criteria: Test article causes no sensitization reaction based on scoring and comparison to control	Pass

Stryker OptaBlate BVN Intraosseous Nerve Ablation System: Access Cannula/ Bevel Stylet Tests	**Test Method Summary**	**Results**
Cytotoxicity – MEM Elution	Standards: ISO 10993-5:2009 ISO 10993- 12:2021 Acceptance Criteria: Test article to be considered non-cytotoxic.	Pass
Irritation – Intracutaneous Reactivity	Standards: ISO 10993-10:2010 ISO 10993-12:2012 Acceptance Criteria: Difference between the test article and control is less than or equal to 1.0	Pass
Acute Systemic Toxicity	Standards: ISO 10993-11:2017 ISO 10993-12:2012 Acceptance Criteria: Test article shows no greater biological reaction than animals treated with control	Pass
Sensitization – Guinea Pig Maximization	Standards: ISO 10993-10:2010 ISO 10993-12:2012 Acceptance Criteria: Test article causes no sensitization reaction based on scoring and comparison to control	Pass

Stryker OptaBlate BVN Intraosseous Nerve Ablation System: Introducer handpiece/ Introducer conduit Tests	**Test Method Summary**	**Results**
Cytotoxicity – MEM Elution	Standards: ISO 10993-5:2009 ISO 10993-12:2012 Acceptance Criteria: Test article to be considered non- cytotoxic.	Pass
Irritation – Intracutaneous Reactivity	Standards: ISO 10993-10:2010 ISO 10993-12:2012 Acceptance Criteria: Difference between the test article and control is less than or equal to 1.0	Pass
Acute Systemic Toxicity	Standards: ISO 10993-11:2017 ISO 10993-12:2012 Acceptance Criteria: Test article shows no greater biological reaction than animals treated with control	Pass
Sensitization – Guinea Pig Maximization	Standards: ISO 10993-10:2010 ISO 10993-12:2012 Acceptance Criteria: Test article causes no sensitization reaction based on scoring and comparison to control	Pass

Electromagnetic compatibility and Electrical Safety Testing

Stryker OptaBlate BVN Intraosseous Nerve 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 60601-1-8; Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- 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 Ed. 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 All applicable clauses from the standard were

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	tested and conform to safety and effectiveness requirements
Alarms	Type testing/conformity testing per IEC 60601-1-8 Ed. 2.2: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	
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 performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	

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.

Stryker OptaBlate BVN Intraosseous Nerve Ablation System Test	**Test Method Summary**	**Results**
Transit	ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems	Pass
Bubble Test	ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Pass
Seal Peel Test	ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials	Pass
Mechanical Testing	Probe Insertion Force Conduit Retraction Force Infusion Flow Rate Tensile Strength Twist Cycle Torsional Stiffness Impact Force	Pass
Dimensional	Meet dimensional specs per product specifications	Pass
Visual Inspection	Ensure non-aged and aged samples free from surface defects and material degradation	Pass
Temperature Accuracy (BVN probe testing)	Accuracy verified by measurements and performance testing covering full functional use range	Pass
Lesion (BVN probe testing)	Measured RF lesion size in ex vivo tissue model (Bovine bone and chicken)	Pass

Clinical Testing

No clinical testing was required to support this submission.

Conclusion

The subject devices, in comparison with the legally marketed predicate, share the same intended use and operating principles. Performance testing demonstrate that the subject devices are at least as safe and effective as the predicate. Any differences between the subject and predicate devices do not raise any new or different types of questions of safety and effectiveness. A determination of substantial equivalence is supported.