February 13, 2026

Merit Medical Systems, Inc.
Sandeep Saboo
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K251802
Trade/Device Name: STAR RF Ablation System
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: January 15, 2026
Received: January 16, 2026

Dear Sandeep Saboo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JAIME RABEN -S

Jaime Raben, Ph.D.
Division 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.

510(k) Number *(if known)*
K251802

Device Name
STAR RF Ablation System

Indications for Use *(Describe)*
The STAR RF Ablation System is intended for ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least six months of conservative care, and is also accompanied by either 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k)#:	K251802

510(k) Summary

General Provisions

Submitter Name:	Merit Medical Systems, Inc.
Address:	1600 West Merit Parkway South Jordan, UT 84095
Telephone Number:	(510) 468-9995
Email:	sandeep.saboo@merit.com
Contact Person:	Sandeep Saboo
Date of Preparation:	12 February 2026
Registration Number:	1721504

Subject Device

Trade Name:	STAR RF Ablation System
Common/Usual Name:	Probe, Radiofrequency Lesion
Classification Name:	Probe, Radiofrequency Lesion

PREDICATE DEVICE

Trade Name:	Intracept Intraosseous Nerve Ablation System
Classification Name:	Probe, Radiofrequency Lesion
Premarket Notification:	K153272
Manufacturer:	Relievant Medsystems, Inc.

Predicate has not been a subject of a design related recall.

Classification

Class:	Class II
Regulation:	21 CFR 882.4725
FDA Product Code:	GXI
Review Panel:	Neurology

Intended Use/Indications For Use

The STAR RF Ablation System is intended for ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least six months of conservative care, and is also accompanied by either 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).

Device Description

The subject device (STAR RF Ablation System) is a bipolar, high frequency electrosurgical system comprising the SpineSTAR Ablation Instrument, MetaSTAR RF Generator, AE Cable, Hand Switch Cable, StabiliT Introducer and PowerCURVE Navigational Osteotome. The subject device is intended to produce lesions by direct application of radiofrequency currents for the relief of chronic low back pain by basivertebral nerve ablation. The MetaSTAR RF Generator applies radiofrequency (RF) energy into the SpineSTAR. StabiliT Introducer is used to create access to the vertebral body and PowerCURVE Navigational Osteotome is used to create a channel to the target site for ablation. During lesion creation, targeted tissue in vertebral body is exposed to RF energy. The application of RF energy causes a thermal reaction at the targeted tissue site to ablate the basivertebral nerve. When used as directed, the SpineSTAR Ablation Instrument is connected to the AE Cable, which is connected to MetaSTAR. A Hand Switch Cable is connected to MetaSTAR to control delivery of RF energy to the target tissue. MetaSTAR monitors the temperature at the periphery of the ablation zone to enable controlled ablation.

Comparison to Predicate

When compared to the predicate device (Relievant Medsystems, Inc. Intracept Intraosseous Nerve Ablation System, the STAR RF Ablation System:

- Has the same indications for use;
- Has the same intended use;
- Has the same mechanism of action and principles of operation; and
- Has similar technological characteristics.

Results of verification and validation demonstrate that minor differences that may exist do not introduce new questions of safety and effectiveness. The subject device is at least as safe and effective as the predicate devices.

Provided in the tables below is a comparison of the subject and the predicate devices. Based on the comparison, the intended/indications for use and technological characteristics of the STAR RF Ablation System are substantially equivalent to the predicate (Relievant Medsystems, Inc. Intracept Intraosseous Nerve Ablation System cleared per K153272).

Intended Use/Indications For Use Comparison:

Device Type→	K251802 SUBJECT Device	K153272 PREDICATE Device
Manufacturer→	**Merit Medical Systems, Inc.**	**Relievant Medsystems, Inc.**
Device Names →	**STAR RF Ablation System**	**Intracept Intraosseous Nerve Ablation System (Relievant Intracept System)**
Class	II	II
Regulation Name	Radiofrequency Lesion Probe	Radiofrequency Lesion Probe
Regulation Number	882.4725	882.4725
Product Code	GXI	GXI
Product Code Description	Probe, Radiofrequency Lesion	Probe, Radiofrequency Lesion
Intended Use	Delivery of RF energy into tissue to ablate tissue and relieve pain.	Delivery of RF energy into tissue to ablate tissue and relieve pain.

Device Type→	K251802 SUBJECT Device	K153272 PREDICATE Device
Manufacturer→	Merit Medical Systems, Inc.	Relievant Medsystems, Inc.
Device Names →	STAR RF Ablation System	Intracept Intraosseous Nerve Ablation System (Relievant Intracept System)
Indications for Use:	The STAR RF Ablation System is intended for ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least 6 months duration that has not responded to at least six months of conservative care, and is also accompanied by either 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 6 months duration that has not responded to at least six months of conservative care, and is also accompanied by either Type 1 or Type 2 Modic changes on an MRI.

Technological Comparison

Device Type →	K251802 SUBJECT DEVICE	K153272 PREDICATE Device
Device Name →	STAR RF Ablation System	Intracept Intraosseous Nerve Ablation System (Relievant Intracept System)
Anatomical site where used	Vertebral body	Vertebral body
Patient population	Adult patient with chronic lower back pain.	Adult patient with chronic lower back pain.
System components	• MetaSTAR RF Generator (RF Generator) • SpineSTAR Ablation Instrument (i.e., RF Probe) • AE Cable • Hand Switch Cable • StabiliT Introducer • PowerCURVE Navigational Osteotome	• RF Generator (Stockert Neuro N50) • Intracept Flexible Bi-Polar Probe (i.e., RF Probe) • Interconnect Cable • Intracept Easy Access Instrument Set (Instrument Set)
RF Probe access to Target location	The RF Probe is used with the StabiliT Introducer and the PowerCURVE for the placement of the RF probe into the target site.	The RF Probe is used with the Access Instrument Set, which allows for the placement of the RF probe into the target site.
Method of Use	Placement of the RF probe at the target tissue; delivery of RF energy into the tissue to achieve tissue ablation (i.e., Cellular necrosis through thermal coagulation).	Placement of the RF probe at the target tissue; delivery of RF energy into the tissue to achieve tissue ablation (i.e., Cellular necrosis through thermal coagulation).
Capability to Monitor Ablation Zone Temperature?	YES	YES
Max Temp Measured At Center of Abl. Zone	• 71°C to 89°C (depending on power setting and device TC used for monitoring the ablation)	• 75°C (Parameter Set #1) • 85°C (Parameter Set #2)
Temp Rise Rate	• 0.2 to 2.9°C/sec (depending on power setting and device TC used for monitoring the ablation)	• 0.5 to 1°C/sec
Ablation Duration	• 18 to 178sec (depending on power setting used for monitoring the ablation)	• 420 to 900secs
Energy Type	Radiofrequency	Radiofrequency

Device Type →	K251802 SUBJECT DEVICE	K153272 PREDICATE Device
Device Name →	**STAR RF Ablation System**	**Intracept Intraosseous Nerve Ablation System** **(Relievant Intracept System)**
Output Power Levels	3, 5, 7.5 and 10W.	Up to 20W
Output Frequency	480 kHz	475 kHz
Principle of operation	Provide bipolar RF energy to the tissue between and around the electrodes to achieve tissue ablation (i.e., cellular necrosis through thermal ablation)	Provide bipolar RF energy to the tissue between and around the electrodes to achieve tissue ablation (i.e., cellular necrosis through thermal ablation)
Electrical Safety EMC	Conforms to IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2	Conforms to IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-2
Information Displayed on Device Screen	• RF Cycle count-down timer • Number of Cycles • TOTAL RF Time (cumulative total) • Distal TC temperature reading • Proximal TC temperature reading • Power Level • Tissue Impedance	• RF Cycle count-down timer • TC reading • Power Delivered • Tissue Impedance • A chart with impedance and power during the RF Cycle.
Shaft OD	3.0 mm	1.98 mm
# of TCs and their position for monitoring ablation zone temperature	Incorporates 1 TC along the shaft at 5 mm from the center of the ablation zone.	Incorporates 1 TC at the center of the ablation zone.
Distal Shaft Design	Can be articulated (i.e., curled/bent for steering using device handle) by the user	Pre-Curved (not articulated by the user)
Shaft Marks	Yes (Circumferential)	Yes (Circumferential)
Cannula/ Introducer	10G Cannula with Bevel and Diamond Tip Stylets	8G Cannula with Bevel and Diamond Tip Stylets
Access Conduit	11G Osteotome with stainless steel shaft	10G Curved Introducer Conduit Peek

Biocompatibility:

Patient contacting materials of the components of STAR RF Ablation System are classified as external communicating devices in contact with tissue/bone/dentin < 24hours and tested for compliance with applicable ISO 10993 standards and in accordance with FDA's biocompatibility guidance and that all acceptance criteria were met.

TEST	TEST METHOD	ACCEPTANCE CRITERIA	RESULT
Cytotoxicity-MEM	ISO 10993-5:2009	Test article to be ≤ Grade 2.	PASS
Sensitization	ISO 10993-10:2021	Test article causes no sensitization reaction based on scoring and comparison to control	PASS
Irritation	ISO 10993-23:2021	Difference between the test article and control is less than or equal to 1.0	PASS
Acute Systemic Toxicity	ISO 10993-11:2017	Test article shows no greater biological reaction than animals treated with control	PASS
Material Mediated Pyrogenicity	ISO 10993-11:2017	If no single animal showed a rise of 0.5°C or more above its baseline temperature, then the extract is judged nonpyrogenic. If the total maximum temperature rise of all three animals exceeded 3.3°C, the extract is judged pyrogenic.	PASS

Performance, Sterilization, Software, and EMC/Electrical Safety Testing:

TEST	TEST METHOD	RESULT
Distribution Testing, Shelf-life (Accelerated Aging)	• ASTM D4169: Standard Practice for Performance Testing of Shipping Containers and Systems • ASTM F1980: Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices • ISO11607-1: Requirements for materials, sterile barrier systems and packaging systems • ASTM F2096: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) • ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials	PASS
Dimensional	Meet dimensional specifications per product specifications (OD, ID, length, shaft marks, protrusion, tip angle, handle orientation)	PASS
Visual Inspection	Ensure test samples are free from surface defects and material degradation	PASS
Temp Accuracy	Temperature measurement accuracy using integrated thermocouples covering full range of use	PASS
Mechanical Testing	• Device insertion in Bone • Device insertion and retraction force through Cannula • Tensile strength • Torque strength (articulation, handle, knob) • Articulation angle • Articulation cycles • Impact force • Lift force • Hammer impulse • Ratchet impulse • Device lifetime • Radiopacity • Luer • Torque limiter	PASS
Electrical Test	• Electrical continuity • Electrical resistance • Hand switch functionality	PASS
Corrosion Test	ASTM F1089: Standard Test Method for Corrosion of Surgical Instruments	PASS
Design Validation	Simulated use testing	PASS
Thermal Effect and comparison to predicate	Measured RF lesion size in ex vivo tissue model.	PASS
Sterilization validation	Sterilization Validation per ISO 11137-1/-2/-3 and 11135	PASS
Software Verification	Testing performed per IEC 62304 and documentation provided per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."	PASS
Electromagnetic compatibility and Electrical Safety	STAR RF Ablation System was evaluated for compliance with the following standards: • 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	PASS

Summary of Substantial Equivalence	Based on the comparison of intended/indications for use and technological characteristics, the subject device is substantially equivalent to the predicate device. The performance tests for each system component and the hardware and software verification and validation testing demonstrate that the subject device meets its performance specifications and will perform as intended in the specified use conditions and that any differences between the subject device and predicate devices do not raise new questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device (Relievant Intracept Intraosseous Nerve Ablation System per K153272).