

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

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"Peripheral Nerve Stimulation (PNS) is the stimulation of a peripheral nerve by tiny electrical impulses. PNS works by delivering low power electrical stimulation to the peripheral nerve masking the sensation of pain. PNS systems can be easily and painlessly programmed to best manage your pain. It is used for chronic ('long term') neuropathic ('nerve') pain. It is often used when other treatments such as medication, physiotherapy or injections haven't worked."

Source:

<https://flipbooks.leedsth.nhs.uk/LN005215.pdf>

"A peripheral nerve stimulator is defined as a device that delivers low-intensity electrical pulses to peripheral nerves, helping to block pain signals and relieve chronic or refractory neurological pain. It consists of an electrode placed near the nerve and is powered by a small battery implanted under the skin."

Source:

<https://www.sciencedirect.com/topics/nursing-and-health-professions/peripheral-nerve-stimulator#:~:text=A%20peripheral%20nerve%20stimulator%20is,battery%20implanted%20under%20the%20skin.&text=How%20useful%20is%20this%20definition?>

1. Axon Therapy is a non-invasive magnetic peripheral nerve stimulation (mPNS) device that delivers brief, focused magnetic pulses to stimulate peripheral nerves for relief of chronic pain.

"The Axon Therapy is a magnetic stimulator system that provides brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves and provide relief of chronic intractable, post-traumatic and post-surgical pain."

"To stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210021>

Manufacturer: Neuralace Medical, Inc. (NeuraLace Medical, Inc.), headquartered in San Diego, CA, USA.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://www.prnewswire.com/news-releases/neuralace-announces-fda-510k-clearance-and-us-launch-of-axon-therapy-peripheral-nerve-stimulation-system-for-chronic-pain-relief-301314525.html>

Website: <https://neuralacemedical.com/> (company)

Primary Indications: Indicated to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities; for use on patients 18 years or older.

"To stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on patients 18 and older."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210021>

Is it FDA Approved?: Yes, FDA-cleared (510(k) clearance as Class II device).

"NeuraLace Medical, Inc. announced today that it has received FDA 510(k) clearance for Axon Therapy to non-invasively stimulate peripheral nerves and provide chronic nerve pain relief."

"The FDA has approved AXON, the first non-invasive, magnetic peripheral nerve stimulation (PNS) device for treating Diabetic Neuropathy (DN) pain" in addition to its previous clearances for other forms of chronic pain.

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Sources:

<https://www.prnewswire.com/news-releases/neuralace-announces-fda-510k-clearance-and-us-launch-of-axon-therapy-peripheral-nerve-stimulation-system-for-chronic-pain-relief-301314525.html>

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://www.meded.co.za/DocumentPart/?id=6178>

FDA Approval Details: Cleared via the 510(k) premarket notification pathway as a Class II device (substantially equivalent to predicate devices). Clearance date: June 11, 2021. 510(k) number: K210021 (with later supplements, e.g., K233364 for updates). Clearance based on substantial equivalence to predicate devices (e.g., K181688 TENS/EMS stimulators and reference magnetic stimulators) for peripheral nerve stimulation; no new questions of safety or effectiveness raised. Expanded indications include chronic painful diabetic peripheral neuropathy.

"The Axon Therapy is substantially equivalent to the predicate devices in terms of intended use, indications for use, design and technological characteristics."

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210021>

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233364>

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233364.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K181688>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181688.pdf

How It Works: The device delivers brief and focused magnetic pulses via a coil applicator placed near the painful area to non-invasively stimulate peripheral nerves, providing pain relief without drugs or surgery; sessions last approximately 13–14 minutes.

"The Axon Therapy is a magnetic stimulator system that provides brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves and provide relief of chronic intractable, post-traumatic and post-surgical pain."

"Axon Therapy uses magnetic peripheral nerve stimulation (mPNS) to deliver a non-invasive treatment for chronic pain". "mPNS delivers a series of biphasic, time-varying magnetic pulses which induce strong electrical fields in the nerve bundles". "By contrast to conventional PNS, Axon Therapy uses magnetic stimulation to engage sensory, pain, and motor fibers mechanistically, providing long-term relief for the root cause of post-trauma and post-surgical neuropathic pain." It achieves this because "the handheld mPNS coil is optimized to deliver specific pulses of a proprietary frequency and wavelength that only activate large diameter nerve fibers (A-alpha and A-beta)."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://www.prnewswire.com/news-releases/neuralace-announces-fda-510k-clearance-and-us-launch-of-axon-therapy-peripheral-nerve-stimulation-system-for-chronic-pain-relief-301314525.html>

<https://www.pharmexec.com/view/fda-clears-neuralace-medical-s-noninvasive-axon-therapy-for-painful-diabetic-neuropathy>

https://www.researchgate.net/publication/384410474_Safety_and_Efficacy_of_Axon_Therapy_SEAT_Study_Utilizing_Magnetic_Peripheral_Nerve_Stimulation_mPNS_for_Treatment_of_Neuropathic_Pain

Frequency Used: "0-2 Hz"

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233364.pdf

Is it Non-Thermal?: Yes. The therapy delivers a high-intensity magnetic field to stimulate nerves strictly via electromagnetic induction, without transferring thermal heat to the patient's skin or tissue. However, because the hardware generates significant internal heat during operation, "The device consists of Magnetic Stimulator, Stimulation Coil, Liquid Cool Unit, and a Cart," and features a thermal shutdown to ensure "the inside temperature of the stimulation coil" does not reach unsafe levels.

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Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233364.pdf

Is it Non-Ionizing?: Yes. The technology utilizes strictly non-ionizing electromagnetic stimulation to safely induce electrical changes in the targeted peripheral nerves, entirely avoiding the cellular-level risks associated with ionizing radiation exposure.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233364.pdf

Side Effects: No new safety or effectiveness concerns identified; the device poses no new risks compared to predicates. Minor and transient effects such as mild discomfort or tingling at the stimulation site may occur. Clinical studies (e.g., SEAT Study) showed low adverse event rates (17.1% treatment vs. 13.3% control), with no device-related serious adverse events or withdrawals.

"The maximum repetition rates... pose no new risk to the patients."

"In conclusion, higher ranges of pulse frequencies... do not raise any new or different questions of safety and effectiveness."

"No device-related serious adverse events or withdrawals."

"The AXON treatment is non-invasive, easy to administer, and has few side effects." Clinical studies such as the SEAT trial found it to be "well-tolerated", with treatment-related adverse events occurring in roughly 8.6% of participants. Due to its powerful magnetic mechanism, it carries strict contraindications and should not be used on "Subjects with implantable 'electrical' medical devices such as a cardiac pacemaker, defibrillator, or insulin pump within four (4) inches or less of the site of pain to be treated by Axon Therapy."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210021.pdf

<https://pmc.ncbi.nlm.nih.gov/articles/PMC11446200/>

<https://www.meded.co.za/DocumentPart/?id=6178>

<https://www.dovepress.com/efficacy-and-safety-of-magnetic-peripheral-nerve-stimulation-for-treat-peer-reviewed-fulltext-article-JPR>

<https://clinicaltrials.gov/study/NCT05620225>

2. ReActiv8 (ReActiv8 Implantable Neurostimulation System) "The ReActiv8 System is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles for the treatment of mechanical chronic low back pain."

"The ReActiv8 System is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3..."

"ReActiv8 is an implantable medical device designed to treat adults with intractable chronic low back pain (CLBP) associated with multifidus muscle dysfunction, which may be evidenced by imaging or physiological testing."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf

<https://www.businesswire.com/news/home/20260204342591/en/Mainstay-Medical-Announces-Exclusive-Coverage-of-ReActiv8-by-Blue-Cross-Blue-Shield-of-North-Dakota>

Manufacturer: Mainstay Medical Holdings plc, headquartered in Dublin, Ireland (with U.S. operations).

Sources:

<https://mainstaymedical.com/>

<https://mainstaymedical.com/wp-content/uploads/2025/09/FY22-Annual-Report-final-with-signatures-1.pdf>

Website: <https://mainstaymedical.com/>

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Primary Indications:

"The ReActiv8 System is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3 as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy including pain medications and physical therapy and are not candidates for spine surgery."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf

Is it FDA Approved?: Yes. "Mainstay Medical Holdings plc ('Mainstay' or the 'Company') today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's Premarket Approval (PMA) application for ReActiv8, its implantable neurostimulation system to treat intractable chronic low back pain."

Sources:

<https://sofinnovapartners.com/news/mainstay-medical-announces-u.s.-fda-approval-of-reactiv8-neurostimulation-system-for-chronic-low-back-pain>

FDA Approval Details:

The ReActiv8 Implantable Neurostimulation System was approved under the Premarket Approval (PMA) pathway. Because it is a totally implanted neurostimulator, it is classified as a Class III device. This means Mainstay Medical had to submit extensive clinical trial data (specifically the ReActiv8-B pivotal study) to definitively prove both the safety and effectiveness of the device before it could be legally marketed in the United States.

Key Dates & PMA Numbers

- PMA Number: P190021
- Date Received by FDA: August 29, 2019
- FDA Approval Date: June 16, 2020
- Product Code: QLK (Stimulator, neuromuscular, lower back muscles, totally implanted for pain relief)

Following the FDA's decision, Jason Hannon, CEO of Mainstay Medical, published a press release regarding the approval scope:

"The FDA approval grants Mainstay the right to market ReActiv8 in the United States as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction... This therapy has the potential to improve quality of life for the most severely-affected patients, and we look forward to making it available to U.S. patients and physicians beginning in the first half of 2021."

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190021>

https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021A.pdf

https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf

<https://clinicaltrials.gov/study/NCT02577354>

https://mainstaymedical.com/wp-content/uploads/2025/10/20200622_Mainstay-Medical_FDA-Approval_PR_22-June-2020.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190021#:~:text=Approval%20for%20the%20ReActiv8%20System,by%20imaging%20or%20physiological%20testing>

How It Works: "One of the primary causes of chronic low back pain is muscle atrophy or poor muscle strength in the low back. After implantation, ReActiv8 delivers electrical stimulation directly to the nerves responsible for those muscles. This nerve stimulation causes controlled muscle contractions. With regular use, muscle strength and control returns and spine stability improves, relieving low back pain at the source." Patients typically self-administer the therapy using a handheld remote for two 30-minute sessions per day.

The ReActiv8 implantable neurostimulation system uses precisely placed leads that, after being surgically positioned, can deliver controlled electrical stimulation to key stabilizing muscles of the lumbar spine. Leads are placed bilaterally (on both sides) for more comprehensive results. Typically, the implantation process takes less than an hour.

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After implantation, the recipient can control the strength and frequency of treatments (typically twice a day for about 30 minutes). Most people notice the benefits of ReActiv8 within a couple months and continue seeing improvement in their symptoms long-term.”

“ReActiv8 is an active implantable medical device designed to treat people with chronic low back pain (CLBP). ReActiv8 provides bilateral electrical stimulation of the L2 medial branch of the dorsal ramus nerve as it crosses the transverse process at L3. This nerve supplies the lumbar multifidus muscle, a key stabilizing muscle of the low back. ReActiv8’s stimulation of the nerve elicits contraction of the muscle, which can lead to improvement in CLBP and its disabling effects.”

How is it Performed?

ReActiv8 therapy involves the implantation of a small neurostimulation device under the skin, near the lower spine. The procedure is performed under local or general anaesthesia and typically follows these steps:

1. **Electrode Placement:** Leads are positioned near the nerves controlling the lumbar multifidus muscle.
2. **Device Implantation:** The neurostimulator is implanted under the skin, usually in the lower back or buttock area.
3. **Activation and Programming:** The device is programmed to deliver electrical pulses, which stimulate the muscle and help restore normal function.
4. **Ongoing Therapy:** Patients undergo therapy sessions at home, activating the device twice a day to retrain the muscle and reduce pain over time.

Sources:

<https://www.kansashealthsystem.com/care/treatments/reactiv8>

<https://sofinnovapartners.com/news/mainstay-medical-announces-u.s.-fda-approval-of-reactiv8-neurostimulation-system-for-chronic-low-back-pain>

<https://saoc.com.au/reactiv8/>

Frequency Used: (Rate) Programmable range: (Minimum value) 1 Hz, (Maximum value) 26 Hz, (Step) 1 Hz, (Nominal value) 20 Hz, (Typical values used in clinical study) 20 Hz

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021C.pdf

Is it Non-Thermal?: Yes. The restorative neurostimulation relies purely on low-voltage electrical impulses to trigger motor nerve action potentials, entirely avoiding the generation or use of thermal heat energy. However, because it is an implanted device containing metal components, the FDA explicitly warns that external thermal treatments like "Diathermy – A medical treatment applied to the outside of the body that uses shortwave, microwave, or ultrasound energy... may cause serious adverse effects from heating of the implanted IPG and leads, perhaps resulting in permanent injury to the surrounding tissue."

“Exposure to strong sources of EMI (Electromagnetic Interference) can result in the following effects:

- Serious injury or death, resulting from heating of the implanted components of the ReActiv8 and damage to surrounding tissue.
- Damage to the ReActiv8, resulting in a loss of or change in stimulation delivery and requiring surgical replacement.
- Operational changes to the ReActiv8 IPG, causing it to turn ON or OFF (particularly if the IPG is enabled for magnet use) or to reset, resulting in loss of stimulation and requiring reprogramming by a clinician.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021C.pdf

https://mainstaymedical.com/wp-content/uploads/2025/09/990103-007_ReActiv8-System-User-Manual-AUS-English_Rev-B-09-16-2025.pdf

Is it Non-Ionizing?: Yes. The implanted pulse generator (IPG) relies on standard battery-powered electrical neurostimulation, emitting non-ionizing electromagnetic energy that completely avoids the cellular-level risks associated with ionizing radiation exposure.

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Sources:

https://mainstaymedical.com/wp-content/uploads/2025/09/990103-001_ReActiv8-System-User-Manual-CE-English_Rev-B-09-16-2025.pdf

Side Effects: Because ReActiv8 involves surgical implantation, "There may also be minor risks associated with the implantation surgery, such as bleeding or infection." Beyond general surgical risks, "The main risk of ReActiv8 is movement of lead away from the target location," which can cause a loss of therapeutic effect or unwanted stimulation in nearby tissues. Furthermore, the device is explicitly contraindicated for patients who are "Unable to operate the system," have "Evidence of cognitive impairment," or are "on blood thinners and unable to be temporarily discontinued for the surgical procedure."

Sources:

<https://www.kansashealthsystem.com/care/treatments/reactiv8>

https://mainstaymedical.com/wp-content/uploads/2025/09/990103-001_ReActiv8-System-User-Manual-CE-English_Rev-B-09-16-2025.pdf

3. Moventis PNS (Peripheral Nerve Stimulator) "Moventis PNS is a wireless peripheral nerve stimulation option designed for drug-free pain relief. It uses an implanted neurotransmitter and an external transmitter to help influence nerve signaling involved in chronic pain."

"The Micron device, at only 7 cm long, is smaller than any PNS implant currently available on the market today, at a volume of only 0.10 cc. Moreover, it provides power levels up to 23.3 mA, which is also more powerful than any other currently available PNS device. The small size and significant power is designed for the rugged tissue impedance needs of peripheral tissue mediums to ensure that long-lasting and continuous therapy will be delivered."

"Moventis PNS is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain originating from peripheral nerves. The therapy utilizes pulsed electrical waveforms to create an electrical energy field that acts on afflicted peripheral nerves to alter the transmission of pain signals from those nerves to the brain. Moventis PNS is comprised of percutaneous Implanted Pulse Generator (pIPG) and a preprogrammed External Transmitter (ETx) worn outside the body over the general area of the pIPG to provide signal and power."

"Moventis PNS is said to be the world's smallest implantable and drug-free peripheral pain nerve stimulator."

"Moventis PNS is the world's smallest implantable, drug free peripheral pain nerve stimulator. "

Sources:

<https://spinemi.com/moventis-pns/>

<https://www.biospace.com/micron-medical-receives-fda-510-k-clearance-for-moventis-pns-a-drug-free-wireless-peripheral-nerve-stimulator-system-for-common-urological-conditions-commercial-launch-underway>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200848>

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

<https://www.nsmedicaldevices.com/deals/pain-specialists-group-micron-medicals/>

<https://www.globenewswire.com/news-release/2021/05/20/2233570/0/en/Micron-Medical-Announces-Sale-of-Peripheral-Pain-Nerve-Stimulator-Division-Moventis-PNS-to-Pain-Specialists-Group-Ltd.html>

Manufacturer: Originally developed by Micron Medical Corporation (also known as Micron Devices LLC). However, in May 2021, the manufacturer announced the sale of "its peripheral pain nerve stimulator franchise, dubbed Moventis PNS" to Pain Specialists Group Ltd.

"Private consortium Pain Specialists Group has acquired the peripheral pain nerve stimulator franchise, dubbed Moventis PNS, from Micron Medical for an undisclosed sum."

"Micron Medical, a privately-held medical device company engaged in the development, manufacture, and commercialization of innovative wireless, minimally invasive electroceutical device solutions, today announced the

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sale of its peripheral pain nerve stimulator franchise (Moventis PNS) to a private consortium, Pain Specialists Group Ltd.”

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

<https://www.nsmedicaldevices.com/deals/pain-specialists-group-micron-medicals/>

<https://www.globenewswire.com/news-release/2021/05/20/2233570/0/en/Micron-Medical-Announces-Sale-of-Peripheral-Pain-Nerve-Stimulator-Division-Moventis-PNS-to-Pain-Specialists-Group-Ltd.html>

Website: No active dedicated site found (company acquired/rebranded); product information via FDA and press releases.

Sources:

<https://www.nsmedicaldevices.com/deals/pain-specialists-group-micron-medicals/?cf-view>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K200848>

Primary Indications: "Moventis PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Moventis PNS is not intended to treat pain in the craniofacial region."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K200848>

Is it FDA Approved?: Yes.

"In September last year, Moventis PNS secured 510(k) clearance from the US Food and Drug Administration (FDA)."

"Micron Medical, a privately-held medical device company engaged in the development, manufacture and commercialization of innovative wireless, minimally invasive, electroceutical device solutions for urological conditions, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for MOVENTIS PNS, a percutaneous implantable pulse generator (pIPG) nerve stimulator system to treat chronic peripheral nerve pain that has therapeutic effects for common urological conditions involving pelvic pain."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K200848>

<https://www.nsmedicaldevices.com/deals/pain-specialists-group-micron-medicals/>

<https://www.biospace.com/micron-medical-receives-fda-510-k-clearance-for-moventis-pns-a-drug-free-wireless-peripheral-nerve-stimulator-system-for-common-urological-conditions-commercial-launch-underway>

FDA Approval Details: The Moventis PNS was cleared under the 510(k) Premarket Notification pathway. The FDA classified it as a Class II medical device under the regulation name "Implanted peripheral nerve stimulator for pain relief" (Regulation Number: 21 CFR 882.5870, Product Code: GZF).

Because it utilized the 510(k) pathway, the Moventis PNS was "cleared" rather than "approved" or "granted." Micron Medical secured this by demonstrating that the device was "substantially equivalent" to predicate peripheral nerve stimulation systems already legally marketed in the United States, such as the StimQ PNS System. Interestingly, around this same time, Micron Medical also pursued the De Novo classification pathway for a sibling device called the PROTECT PNS, specifically targeting overactive bladder (OAB).

Key Dates & Numbers

- 510(k) Number: K200848
- Date Received by FDA: May 19, 2020
- FDA Clearance Date: August 14, 2020

"Following performance testing, it has been determined that Moventis PNS is substantially equivalent to legally marketed predicate devices for the therapeutic relief for chronic, intractable pain of peripheral nerve origin."

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Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200848>

How It Works: "Moventis PNS™ is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain originating from peripheral nerves. The therapy utilizes pulsed electrical waveforms to create an electrical energy field that acts on afflicted peripheral nerves to alter the transmission of pain signals from those nerves to the brain. Moventis PNS is comprised of percutaneous Implanted Pulse Generator (pIPG) and a pre-programmed External Transmitter (ETx) worn outside the body over the general area of the pIPG to provide signal and power."

Unlike some older neuromodulation systems that require large implanted batteries, the Moventis is a wireless system utilizing Radio Frequency (RF). It relies on two primary components communicating through the skin:

"Moventis PNS is comprised of percutaneous Implanted Pulse Generator (pIPG) and a pre-programmed External Transmitter (ETx) worn outside the body over the general area of the pIPG to provide signal and power."

The implanted portion (the pIPG) is a tiny lead with a built-in receiver and electrodes that is placed next to the targeted nerve. Because it lacks an internal battery, it relies on "RF wireless transmission of energy to produce stimulation." The external transmitter (ETx) sends a 915 MHz radiofrequency signal through the skin to continuously power the implant and control the pulsing of the electrical field.

"RF wireless transmission of energy to produce stimulation. ETx sends pulsed RF signal on carrier frequency (915MHz) to pIPG."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

Frequency Used: "RF wireless transmission of energy to produce stimulation. ETx sends pulsed RF signal on carrier frequency (915MHz) to pIPG."

"Pulse Frequency 5 to 1,500 Hz"

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

Is it Non-Thermal?: Yes. The system utilizes "RF wireless transmission of energy to produce stimulation," functioning entirely as a neuromodulation device to alter nerve signaling without the generation or transfer of thermal heat energy to the patient's surrounding tissues

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

Is it Non-Ionizing?: Yes. The external transmitter utilizes standard radiofrequency microwave energy (915 MHz) to power the implant and deliver its electrical pulses. This relies exclusively on non-ionizing radiation and carries none of the cellular-level risks associated with ionizing radiation exposure.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

Side Effects: Like any implanted medical device, there are surgical and hardware-related risks. The FDA's MAUDE (Manufacturer and User Facility Device Experience) database lists potential adverse events associated with the device's use, which can include "Material Erosion," "Skin Erosion," "Post Operative Wound Infection," and "Skin Infection."

"Of 1149 unique reports, procedural complications were most common (31.3%), followed by device-related complications (30.9%), and patient complaints (24.02%). Reports that did not fit the categories described were "Other" complications (10.97%). The most common procedural complications were infections (26.8%), and the most common device-related complications were lead migration (10.5%), erosion (8.09%), and electric shock (4.53%)."

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Explant was the most common management technique (46.3%). Other nonsurgical management (22.9%) and surgical revision (17.7%) were also common.”

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200848.pdf

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=11281130&pc=GZF

<https://pubmed.ncbi.nlm.nih.gov/41097862>

4. Nalu Neurostimulation System is an implantable neurostimulation device that delivers electrical stimulation to the spinal cord or peripheral nerves for the management of chronic intractable pain of the trunk and/or limbs, using a miniature battery-free micro-implantable pulse generator (micro-IPG) powered externally.

"The Nalu Neurostimulation System is a multi-component, non-integrated implant. It includes an implanted microstimulator, a separate electrode array, and an externally worn therapy disc—providing a small, flexible, and adaptable solution for patients while reducing the need for frequent interventions." The system features a miniaturized, battery-free Implantable Pulse Generator (mIPG) that is powered wirelessly by the external disc.

“The Nalu Neurostimulation System (also referred to as the “Nalu System”) is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The Nalu Neurostimulation system incorporates a miniature implanted neurostimulator, powered by an externally worn Therapy Disc device. Similar to the predicate StimQ, the Nalu Neurostimulation therapy utilizes pulsed electrical current to create an energy field that acts on the peripheral nerves to inhibit the transmission of pain signals to the brain. The Nalu System may be implanted following a successful trial period using the Nalu Neurostimulation trial system.”

Sources:

<https://nalumed.com/providers/>

<https://nalumed.com/>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183579.pdf

Manufacturer: Nalu Medical, Inc. (Note: In late 2025, Boston Scientific announced a definitive agreement to acquire Nalu Medical, with the transaction expected to close in early 2026).

“Nalu Medical is now part of Boston Scientific”

Sources:

<https://nalumed.com/>

<https://adventls.com/category/press-release/nalu-medical/>

Website: <https://nalumed.com/>

Primary Indications:

Spinal Cord Stimulation:

This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Peripheral Nerve Stimulation:

This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Nalu Neurostimulation System for PNS is not intended to treat pain in the craniofacial region. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

Sources:

<https://nalumed.com/providers/>

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

<https://nalumed.com/patients/spinal-cord-stimulator/>

<https://nalumed.com/patients/peripheral-nerve-stimulator/>

Is it FDA Approved?: Yes. "The Nalu Neurostimulation System is currently FDA cleared for spinal cord stimulation and peripheral nerve stimulation indications."

Sources:

<https://nalumed.com/providers/>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233801>

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

FDA Approval Details:

FDA Regulatory Pathway & Classification

- **Pathway:** The Nalu Neurostimulation System was cleared under the 510(k) Premarket Notification pathway.
- **Classification:** It is classified as a Class II medical device, allowing it to bypass the stricter Premarket Approval (PMA) process required for Class III life-sustaining devices.
- **Clearance vs. Approval:** The FDA "cleared" rather than "approved" the device, meaning Nalu Medical successfully demonstrated that their micro-IPG system is "substantially equivalent" in safety and effectiveness to legally marketed predicate devices.
- **Dual Clearance:** Uniquely, the system holds clearances under two distinct product codes:
 - Spinal Cord Stimulation (SCS): Product Code GZB (Stimulator, Spinal-Cord, Implanted) under Regulation Number 21 CFR 882.5880.
 - Peripheral Nerve Stimulation (PNS): Product Code GZF (Implanted peripheral nerve stimulator for pain relief) under Regulation Number 21 CFR 882.5870.

510(k) Premarket Notification Clearance Timeline

Medical devices undergo continuous updates to hardware, software, and labeling. Here is the chronological 510(k) history for the Nalu System:

- K183047 (March 22, 2019): The foundational clearance specifically for Spinal Cord Stimulation (SCS).
- K183579 (March 29, 2019): The foundational clearance specifically for Peripheral Nerve Stimulation (PNS).
- K191435 (September 06, 2019): An updated PNS clearance to include integrated and ported lead kits.
- K203547 (March 25, 2021): A unified clearance covering system modifications for both SCS and PNS applications under a single regulatory submission.
- K221376 (June 10, 2022): Updated clearance for further system modifications across both SCS and PNS modalities.
- K232415 (August 21, 2024): Clearance specifically for updated Nalu Neurostimulation Kits and Lead Kits for PNS.
- K233801 (August 23, 2024): The most recent major system update clearance for both SCS and PNS. (Note: Following these 2024 clearances, Boston Scientific announced its agreement to acquire Nalu Medical in late 2025).

Other Regulatory Label Expansions

- In December 2020, Nalu announced it has received FDA Clearance for 1.5T Full-Body MRI Scanning In Patients With Nalu Neurostimulation System Implants.
"Nalu Medical, Inc. ("Nalu"), a company that provides miniaturized neuromodulation implants for the treatment of intractable chronic pain, has received FDA 510(k) clearance for expanded labeling that allows for full-body 1.5 Tesla (T) magnetic resonance imaging (MRI) in individuals with select Nalu Spinal Cord Stimulation (SCS) implants. This clearance is retroactive to currently implanted SCS patients and considered MRI-Conditional. With a conditional classification, MRI scans can be safely administered under certain conditions, including specific requirements with respect to the type of MRI scanner, implant configuration and anatomical location, among other. The MRI safety labeling also includes 1.5T and 3T scans of the head and extremities for SCS and Peripheral Nerve Stimulation (PNS) Systems."

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

- In January 2025, it was announced that Nalu expanded MRI-conditional labeling for Peripheral Nerve Stimulation with FDA Clearance for Whole-Body MRI.
“Nalu Medical announces the FDA clearance for expanded labeling of its Peripheral Nerve Stimulation (PNS) System, now approved for whole-body MRI-conditional use. This clearance provides physicians with greater flexibility in treating chronic pain, minimizing MRI-related limitations. With the Nalu Neurostimulation System’s new and expanded MRI-conditional status, pain specialists can confidently offer personalized care without compromising future diagnostic imaging needs.”
“The US Food and Drug Administration (FDA) has granted an extended label clearance for whole-body MRI-conditional use to Nalu Medical’s neurostimulation system under its previously cleared indication for peripheral nerve stimulation (PNS) therapy.”

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K183047>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183047.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K183579>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183579.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191435>

https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191435.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K203547>

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203547.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221376>

https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221376.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232415>

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K232415.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233801>

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

<https://adventls.com/category/press-release/nalu-medical/>

<https://nalumed.com/nalu-receives-fda-clearance-for-1-5t-full-body-mri-scanning-in-patients-with-nalu-neurostimulation-system-implants/>

<https://nalumed.com/nalu-expands-mri-conditional-labeling-for-peripheral-nerve-stimulation-with-fda-clearance-for-whole-body-mri/>

<https://www.medicaldevice-network.com/news/fda-grants-nalu-medical-mri-conditional-label-extension-for-neurostim-system/>

How It Works: "The Nalu System incorporates a miniature implantable pulse generator (IPG), powered by an externally worn Therapy Disc device. The Nalu System therapy utilizes pulsed electrical current to create an energy field that acts on peripheral nerves or central nerves to inhibit the transmission of pain signals to the brain." The patient uses a smartphone app to control the therapy parameters delivered by the Therapy Disc, which attaches to the skin directly over the implant via a hypoallergenic adhesive clip.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

<https://nalumed.com/providers/>

Frequency Used: “Pulse Frequency 2 Hz to 1500 Hz”

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

Is it Non-Thermal?: Yes. The micro-implant utilizes standard pulsed electrical waveforms delivered directly to the targeted nerves. It operates entirely via electrical neuromodulation and does not generate or transfer therapeutic thermal heat energy to the patient's surrounding tissues.

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

Is it Non-Ionizing?: Yes. The device functions via an external Therapy Disc that safely transmits power and signals to the implant via non-ionizing radiofrequency (RF) waves. The electrical stimulation itself is also strictly non-ionizing, posing none of the cellular-level risks associated with ionizing radiation exposure.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233801.pdf

Side Effects:

Below is a list of side effects that may occur during surgery and/or during standard spinal cord or peripheral nerve stimulation:

- Undesirable changes in stimulation sensation and/or location with or without patient movement.
- Persistent post-surgical pain at hardware implantation sites.
- Seroma or hematoma at surgery sites.
- Spinal cord injury and or compression with subsequent neurological deficits - permanent or temporary.
- Stroke.
- Lead migration, causing the electrodes to move from the intended location.
- Implantable Pulse Generator migration, which may or may not require surgical intervention.
- Fracture of the Lead(s) or failure of other system components, which may result in the loss of stimulation or untoward stimulation induced dysesthesias
- Allergic or rejection reaction to the anaesthesia, implanted components, or external components.
- Reaction to the selected antibiotics or to the Nalu device including: rash, diarrhea, abdominal pain, nausea/vomiting, dizziness, headaches, hypersensitivity (allergic) reactions
- Undesirable skin problems such as infection, irritation, blistering, tearing or allergic reactions that may occur during the use of any wearable component of the Nalu Neurostimulation System.
- Skin irritation, including redness, itchiness, and bumpiness
- Infection at implant site that may or may not require hospitalization and require treatment with antibiotic therapy or surgical intervention
- Cerebral spinal fluid (CSF) leak inclusive of those requiring active medical intervention.
- Inadequate pain relief or increase in pain following system implantation
- Wound complications that may require medical intervention inclusive of surgical management.
- Thromboembolic events requiring medical intervention; inclusive of deep vein thrombosis and pulmonary embolism.
- Death and/or catastrophic neurological complications.
- Anesthetic complications - e.g. nausea, urinary retention.
- Headache.
- Bleeding.
- Excessive fibrotic reaction to device leading to pain and/or new pain symptoms.
- Unexpected stimulation effects including but not limited to: chest wall stimulation, muscle stimulation, tremor, dyskinesia, superficial pain, cramping, light-headedness and metallic taste.
- Weakness.
- Numbness.
- Clumsiness.
- Tissue damage.
- Nerve damage.
- Paralysis.
- Swelling.

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

- Sensory loss.
- Discomfort during the treatment.
- Skin erosion around the Nalu Implantable System or at the site of the Nalu wearable devices.
- Battery failure
- Lead breakage requiring replacement of the Lead.
- Electromagnetic interference causing a change in System performance.
- Loss of therapeutic effect despite a functioning system.
- Hardware malfunction requiring replacement of the neurostimulator components.
- Pain from a non-injurious stimulus to the skin (allodynia).
- An exaggerated sense of pain (hyperesthesia).
- Change in stimulation that are possibly related to tissue changes around the electrodes, shifts in electrode position, loose electrical connections, and Lead or extension fractures which have been described by some patients as uncomfortable stimulation (a jolting or shocking sensation).
- Formation of reactive tissue in the epidural space around the Lead can result in delayed spinal cord compression and paralysis, requiring surgical intervention. Time to onset can range from days to many years after implant.
- Arrhythmia.
- Cardiac arrest.
- Intracranial hypotension.
- Fracture of the lead(s) or failure of other system components.
- Loss of therapy or unpleasant paraesthesia.

Sources:

<https://nalumed.com/wp-content/uploads/2021/03/IPG-Surgical-Manual-MA-000071-Rev-E.pdf>

5. SPRINT PNS (Peripheral Nerve Stimulation) System is a temporary, non-surgical, minimally invasive device that delivers electrical stimulation to targeted peripheral nerves via percutaneously placed leads connected to an external stimulator for the management of chronic and acute pain.

“The Sprint PNS System is comprised of a percutaneous electrode placed via an introducer needle in proximity to a target peripheral nerve associated with a painful area and a wearable external Pulse Generator (stimulator) that delivers stimulation therapy to the percutaneous electrode. The Sprint PNS System provides peripheral nerve stimulation (PNS) therapy to relieve pain. The percutaneous electrode (MicroLead) is a sterile, flexible, coiled, stainless steel wire designed to be percutaneously inserted via an introducer needle and remain indwelling for the duration of the therapy (up to 60 days). The Pulse Generator and accessory components provide tools for percutaneous MicroLead placement, stimulator programming by the clinician, and stimulator use by the patient.”

"The SPR SPRINT PNS System is a 60-day PNS solution for durable pain relief with more data and more applications than any other PNS system available. Uniquely designed to selectively stimulate targeted peripheral nerve fibers for up to 60 days, the SPRINT PNS System delivers a low-risk, non-surgical, minimally invasive and drug-free pain treatment option proven in clinical studies to provide significant and sustained relief from moderate to severe acute and chronic pain." It involves a MicroLead that is "implanted and then removed after treatment of up to 60 days," providing "a 60-day percutaneous treatment that delivers long-term relief without a permanent implant".

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf

<https://www.sprpainrelief.com/hcp/sprint-pns-system>

<https://thepaincenterinc.com/Portals/0/PDFs/SPRINT-PNS.pdf>

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

Manufacturer: SPR Therapeutics, Inc., headquartered in Cleveland, OH, USA.

Sources:

<https://www.sprpainrelief.com/sprint-pns-system>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf

<https://www.sprtherapeutics.com/>

Website: <https://www.sprtherapeutics.com/>

Primary Indications: "The SPRINT Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days for:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The SPRINT PNS System is not intended to be placed in the region innervated by the cranial and facial nerves."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223306.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223306>

Is it FDA Approved?: Yes.

"SPR Therapeutics has obtained clearance from the U.S. Food and Drug Administration (FDA) of a broader indication for use for its SPRINT Peripheral Nerve Stimulation (PNS) System."

Sources:

<https://www.sprpainrelief.com/press-releases/fda-clearance-expanded-indication-sprintr-pns-system-now-enables-treatment-areas>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf

FDA Approval Details:

FDA Regulatory Pathway & Classification

- **Pathway:** The SPRINT PNS System was cleared under the 510(k) Premarket Notification pathway.
- **Classification:** The FDA classifies it as a Class II medical device under the product code NHI (Transcutaneous electrical nerve stimulator for pain relief / Percutaneous Electrical Nerve Stimulation).
- **Clearance vs. Approval:** By utilizing the 510(k) pathway, the FDA "cleared" rather than "approved" the device. SPR Therapeutics secured this by proving their system is "substantially equivalent" in safety and effectiveness to legally marketed predicate devices, bypassing the Premarket Approval (PMA) required for Class III permanent implants.
- **Unique Device Profile:** Unlike permanently implanted PNS systems (such as Nalu or StimRouter), the SPRINT PNS System is uniquely classified and cleared as a temporary, 60-day implant. It utilizes a percutaneous, coiled "MicroLead" wire that remains indwelling for a maximum of 60 days before being completely removed. The clinical goal is to provide sustained, long-term pain relief that endures well beyond the 60-day therapy window by "reconditioning" the central nervous system.

510(k) Premarket Notification Clearance Timeline

As SPR Therapeutics updated the system's hardware, lead securement mechanisms, and anatomical indications, it accumulated a detailed 510(k) history:

- **K181422 (July 31, 2018):** The foundational clearance for the SPRINT PNS System. This clearance allowed for up to 60 days of use, but was specifically restricted to treating pain in the back and/or extremities.
- **K202660 (January 22, 2021):** A clearance for design modifications aimed at improving the ease of use and reliability of the system, though it retained the anatomical restrictions of the 2018 clearance.
- **K211801 (October 2021):** A major regulatory milestone. The FDA cleared an expanded indication that officially removed the restriction limiting the device to the back and extremities. This allowed the SPRINT System to be used in areas of the head, neck, and the front of the torso (with the specific exception of cranial and facial nerves).
- **K223306 (January 2023):** The most recent major clearance, which included technological advancements to the system's lead securement mechanism. Following this clearance, SPR Therapeutics also rolled out expanded labeling that lowered the minimum patient age requirement from 21 down to 18 years old.

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

“The patient population that can be treated using SPRINT PNS has expanded to include those age 18 and up, previously age 21 and up, increasing the number of patients that can benefit from this unique approach to peripheral nerve stimulation.”

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K181422>

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K202660>

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202660.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K211801>

https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211801.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm?ID=K223306>

https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223306.pdf

[https://www.sprpainsrelief.com/press-releases/spr-receives-510k-clearance-technological-advancements-and-expanded-intended-](https://www.sprpainsrelief.com/press-releases/spr-receives-510k-clearance-technological-advancements-and-expanded-intended-patient#:~:text=The%20patient%20population%20that%20can,approach%20to%20peripheral%20nerve%20stimulation.)

[patient#:~:text=The%20patient%20population%20that%20can,approach%20to%20peripheral%20nerve%20stimulation.](https://www.sprpainsrelief.com/press-releases/spr-receives-510k-clearance-technological-advancements-and-expanded-intended-patient#:~:text=The%20patient%20population%20that%20can,approach%20to%20peripheral%20nerve%20stimulation.)

How It Works: "With the SPRINT System, a tiny MicroLead not much thicker than the diameter of a strand of hair, is placed to stimulate the targeted nerve. A small device sends gentle pulses through the MicroLead to stimulate the nerve. A simple handheld remote allows you to control the stimulation level to find a setting that works best for you. After 60 days, the MicroLead is removed and treatment is complete." "This stimulation is believed to interrupt the pain signals, boost the healthy non-pain signals, and help rebalance the information the brain receives."

Sources:

<https://www.americanpainconsortium.com/treatments/neuromodulation/sprint-pns-peripheral-nerve-stimulation/>

<https://visaliavips.com/peripheral-nerve-stimulator>

Frequency Used:

“Stimulation utilizes an asymmetric charge-balanced biphasic pulse train (amplitude: 1 – 30 mA; pulse width: 10 – 200 μ s; frequency: 5 – 150 Hz).”

“Frequency, Hz 5-150”

Sources:

<https://www.painphysicianjournal.com/current/pdf/NzY1OQ==/152>

https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223306.pdf

Is it Non-Thermal?: Yes. The therapy relies entirely on "tiny electrical pulses" sent through the percutaneous MicroLead to replace pain signals. It functions strictly through electrical neuromodulation and completely avoids the generation or transfer of thermal heat energy to the patient's tissues.

Sources:

<https://visaliavips.com/peripheral-nerve-stimulator>

Is it Non-Ionizing?: Yes. The external, battery-powered pulse generator relies entirely on non-ionizing, low-level electrical currents transmitted through the MicroLead, posing none of the cellular-level risks associated with ionizing radiation exposure.

Sources:

<https://clinicaltrials.gov/study/NCT03179202>

Side Effects: Because the lead pierces the skin but is not fully implanted, the surgical risks are relatively low compared to permanent implants. "In clinical studies, the most common adverse events were skin irritation and erythema" with "skin irritation due to adhesive components as the most reported event." Medical providers also note that "Some tenderness or soreness at the implant site is normal and usually resolves in a few days". The treatment is strictly contraindicated for patients who "Have a deep brain stimulation (DBS) system already implanted," "Have an active cardiac implant, such as a pacemaker or defibrillator," or "Have a tape or adhesive allergy."

FDA Approved EMF Devices

Peripheral Nerve Stimulation (PNS)

Sources:

<https://www.sprpainrelief.com/hcp/sprint-pns-system>

<https://www.americanpainconsortium.com/treatments/neuromodulation/sprint-pns-peripheral-nerve-stimulation/>

<https://www.neurosurgeryone.com/treatment/sprint-peripheral-nerve-stimulation/>