May 28, 2026

Algiamed Technologies USA, Inc.
Irina Proutski
Regulatory Affairs Consultant
801 International Pkwy. 5th Floor
Lake Mary, Florida 32746

Re: K252712
Trade/Device Name: STIMPOD NMS460 Nerve Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: December 15, 2025
Received: December 15, 2025

Dear Irina Proutski:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

For Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252712

Device Name
STIMPOD NMS460 Nerve Stimulator

Indications for Use *(Describe)*
The STIMPOD NMS460 Nerve Stimulator is a Transcutaneous Electrical Nerve Stimulation (TENS) device used for symptomatic relief and management of chronic intractable pain conditions.
The device is also used as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain problems, as well as adjunct for pain control due to rehabilitation.
The device provides temporary relief of mild to moderate neuropathic pain associated with diabetic peripheral neuropathy of the lower extremities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with requirements of 21 CFR 807.87 and 807.92.

1. Submitter

Date prepared	28 May 2026
Name	Algiamed Technologies USA Inc
Address	801 International Pkwy 5th Floor Lake Mary, FL 32746 United States
Contact Person	Irina Proutski
Contact e-mail	irina@algiamed.com

2. Device

Device Name	STIMPOD NMS460 Nerve Stimulator
Classification Name	Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890)
Device Class	Class II
Product code	GZJ

3. Predicate Device

Model Name	STIMPOD NMS460 Nerve Stimulator
Manufacturer	Xavant Technology (Pty) Ltdt
Submission Number	K161091
Classification Name	Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890)
Device Class	Class II
Product code	GZJ

4. Device Description

The STIMPOD NMS460 is a handheld, low frequency neuromodulation Transcutaneous Electrical Nerve Stimulation (TENS) device used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain, as well as an adjunct for pain control due to rehabilitation exercises.

The STIMPOD NMS460 offers two types of waveforms for the management of pain. The first is a Monophasic Square Wave, which is typical of normal TENS machines. The second waveform is a Hybrid RF waveform which consists of a Monophasic Square Wave with a superimposed Radio Frequency waveform.

The device is provided with a stimulation cable, conductive electrode gel and a printed copy of the Instructions for Use. The stimulation cable is a point-contact surface electrode intended for use during stimulation sessions to target and stimulate specific nerves. A nerve fiber is excited through the focused current controlled delivery of a patented stimulation pattern that consists of high frequency, shaped sinusoidal burst at 130kHz with a stimulation pulse width of 100µs and 200µs, intensity (1mA – 30mA) and repetition rate (1Hz – 10Hz).

5. Indications for Use

The STIMPOD NMS460 Nerve Stimulator is a Transcutaneous Electrical Nerve Stimulation (TENS) device used for symptomatic relief and management of chronic intractable pain conditions.
The device is also used as an adjunctive treatment in the management of post-surgical pain, post traumatic acute pain problems, as well as adjunct for pain control due to rehabilitation.
The device provides temporary relief of mild to moderate neuropathic pain associated with diabetic peripheral neuropathy of the lower extremities.

6. Comparison of Technological Characteristics with the Predicate Device

The subject device has identical intended use, technological characteristics, mechanism of action and operating principles compared to the predicate device. Both the subject and the predicate devices utilize an application of electrical current to stimulate peripheral nerves to achieve pain relief. Both devices offer the same two types of waveforms for the management of pain. The subject device has nearly identical output specifications as the predicate device – high frequency, shaped sinusoidal burst at 130kHz with a stimulation pulse width of 100µs and 200µs, intensity (1mA – 30mA) and repetition rate (1Hz – 10Hz).
The purpose of this submission is to include a specific indication for use (management of neuropathic pain due to diabetic neuropathy). The electrical stimulation parameters and other characteristics have not changed between the devices.

Characteristics	**NMS460 (subject device)**	**NMS460 (primary device)**	**Substantial equivalence**
510(k)	K252712	K161091	
Manufacturer	Algiamed Technologies USA Inc	Xavant Technology (Pty) Ltd	Different. The 510(k) for the device was transferred from Xavant Technology (Pty) Ltd to Algiamed Technologies USA Inc in 2025.
Intended Use/ Indications for Use statement			
Intended Use	The STIMPOD NMS460 Nerve Stimulator is a Transcutaneous Electrical Nerve Stimulation (TENS) device that uses electrical impulses to stimulate a nerve of interest and relieve the pain.	The STIMPOD NMS460 Nerve Stimulator is a Transcutaneous Electrical Nerve Stimulation (TENS) device that uses electrical impulses to stimulate a nerve of interest and relieve the pain.	same
Indications for Use	The STIMPOD NMS460 is a Transcutaneous Electrical Nerve Stimulation device used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic pain problems, as well as an adjunct for pain control due to rehabilitation. The device provides temporary relief of mild to	The STIMPOD NMS460 is a Transcutaneous Electrical Nerve Stimulation device used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical pain, post traumatic pain problems, as well as an adjunct for pain control due to rehabilitation.	Different. The Indications for Use statement of the STIMPOD NMS460 is not identical to that of the predicate device. The only difference is the inclusion of “temporary relief of mild to moderate neuropathic pain

	moderate neuropathic pain associated with diabetic peripheral neuropathy of the lower extremities.		associated with diabetic peripheral neuropathy of the lower extremities," which is supported by clinical data. The difference does not alter the intended therapeutic use of the device (transcutaneous electrical stimulation of peripheral nerves for pain relief), nor does it raise different questions of safety or effectiveness relative to the predicate. Both the subject and predicate devices have the same intended use of symptomatic relief and management of pain through delivery of short-term electrical stimulation
Rx vs OTC	Prescription Use	Prescription Use	same
Contraindications	• Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death • Do not use this device on patients whose pain syndromes are undiagnosed	• Known neurological disorders • Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death • Do not use this device on patients whose pain syndromes are undiagnosed	Different. Removal of this contraindication does not lead to different questions of safety or effectiveness
Single use electrodes	Yes	Yes	same
Technological Characteristics			

Electrical classification	IEC 60601-1	IEC 60601-1	same
Device classification	Class IIa, Type BF	Class IIa, Type BF	same
Product dimensions	145mm x 90mm x 30mm	145mm x 90mm x 30mm	same
Power supply	4 x AAA alkaline batteries	4 x AAA alkaline batteries	same
Power consumption	17mA	17mA	same
Stimulating Frequency	1, 2, 5 and 10Hz	1, 2, 5 and 10Hz	same
Waveform	Monophasic square wave and Hybrid RF (monophasic square wave with a superimposed Radio Frequency waveform)	Monophasic square wave and Hybrid RF (monophasic square wave with a superimposed Radio Frequency waveform)	same
Load impedance	0 – 7.0 kOhm	0 – 7.0kOhm	same
Current range	0 – 30mA	0 – 30mA	same
Pulse width	0.1ms, 0.2ms	0.1ms, 0.2ms	same
Controls	Control dial	Control dial	same
Output regulation	Device software and control dial	Device software and control dial	same

Number of output modes	1	1	same
Number of waveforms	2	2	same
Number of output channels	1	1	same
Automatic overload detection	Yes	Yes	same
Automatic no-load detection	Yes	Yes	same
Automatic shut-off	Yes	Yes	same
User Override control	Yes	Yes	same
Device display	LED screen	LED screen	same
Device materials	ABC plastic	ABC plastic	same
Electrode materials	SSt 316L	SSt 316L	same
Current/voltage source	Current source	Current source	same
Maximum stimulation voltage	220V	220V	same
Maximum output current	43.7mA	43.7mA	same
Maximum average current (over primary phase)	29.85mA	29.85mA	same
Duration of primary phase	206µs	206µs	same
Pulse duration	206µs	206µs	same
Maximum average phase charge	6.06µC @500 Ohm	6.06µC @500 Ohm	same
Net charge	6.06µC	6.06µC	same
Maximum current density	93.28µA/mm^2 @500 Ohm	93.28µA/mm^2 @500Ohm	same
Maximum average power density	71.5µW/mm^2 @500 Ohm 591.8µW/mm^2 @5 kOhm	71.5µW/mm^2 @500 Ohm 591.8µW/mm^2 @5 kOhm	same
Treatment timer maximum	99min	99min	Same

7. Performance Data

Non-Clinical

No non-clinical testing has been conducted for the subject device because non-clinical testing was conducted for the predicate device (K161091), which included electrical safety, electromagnetic compatibility, biocompatibility evaluation and software verification and validation. As no technological changes have been made to the subject device, no additional non-clinical performance testing is required in this submission.

Clinical Data

Safety and effectiveness of STIMPOD NMS460 for temporary relief of mild to moderate neuropathic pain associated with diabetic peripheral neuropathy of the lower extremities is supported by a single-blind, randomized, prospective, placebo-controlled clinical study.

The primary effectiveness endpoint was a validated neuropathic pain assessment tool - Douleur Neuropathique 4 scores, and the secondary effectiveness endpoint was Brief Pain Inventory worst pain severity scores. The primary and secondary effectiveness endpoints were assessed immediately post-treatment and at 1, 3 and 6-month follow-up.

The study demonstrated a statistically significant reduction in neuropathic pain in the active treatment group compared to placebo. The treatment effect on pain severity was confirmed to be independent of baseline patient characteristics. The study did not report any procedure- or device-related adverse events.

8. Conclusion

The STIMPOD NMS460 Nerve Stimulator has the same technological characteristics as the predicate device (K161091), no technological changes have been made. The Intended Use of the subject device is as same as the predicate device. A new indication (temporary relief of mild to moderate neuropathic pain associated with diabetic peripheral neuropathy of the lower extremities) was supported by clinical data and does not raise different questions of safety or effectiveness. It can be concluded that STIMPOD NMS460 Nerve Stimulator is substantially equivalent to the identified predicate device (K161091).