February 27, 2026

Epineuron Technologies, Inc.
Mike Willand
Chief Technology Officer, Co-Founder
1875 Buckhorn Gate
Unit 602
Mississauga, ON L4W5P1
Canada

Re: K253536
Trade/Device Name: Evala Nerve Stimulator (EPNR002)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: January 29, 2026
Received: January 29, 2026

Dear Mike Willand:

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,

SHUCHEN PENG -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253536

Please provide the device trade name(s).

Evala Nerve Stimulator (EPNR002)

Please provide your Indications for Use below.

Evala is a single-use device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K253536

510(k) Summary

Prepared on: 2026-02-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Epineuron Technologies Inc.
Applicant Address	1875 Buckhorn Gate Unit 602 Mississauga ON L4W5P1 Canada
Applicant Contact Telephone	+1-905-206-0466
Applicant Contact	Mike Willand
Applicant Contact Email	mwilland@epineurontech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Evala Nerve Stimulator (EPNR002)
Common Name	Surgical nerve stimulator/locator
Classification Name	Stimulator, Nerve
Regulation Number	874.1820
Product Code(s)	ETN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150005	Checkpoint Head & Neck	ETN

Device Description Summary

21 CFR 807.92(a)(4)

The Evala Nerve Stimulator is a small handheld device used by a surgeon to deliver electrical stimulation intraoperatively to test nerve integrity and muscle excitability. This is a sterile disposable device designed to be simple to use with one-handed control.

The device employs a bipolar stimulating probe to deliver a charge-balanced, biphasic electrical stimulus to nerve tissue, allowing surgeons to monitor the resulting muscle responses. The device contains embedded firmware that controls the function of the stimulator. The firmware cannot be modified by the user. The stimulator is powered by an internal battery which is not user replaceable. The surgeon is notified of stimulation delivery and device status via the visual indicators at the front of the device and vibratory (haptic) feedback felt on the body of the device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Evala is a single-use device intended to provide electrical stimulation of exposed motor nerves or muscle tissue to locate and identify nerves and to test nerve and muscle excitability.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The predicate device (Checkpoint Head & Neck) has the same indications for use as the Evala Nerve Stimulator.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate device are similar based on the following technological elements:

hand-held, sterile, single-use, disposable, integral stimulus probe, battery powered, intended for prescription use, regulated current, electrode material, software/firmware/microprocessor control, LED based visual indicator to notify the user that selected stimulus is being delivered to the probe, and biphasic rectangular waveform with no net DC current.

The differences between the two devices include the bipolar probe configuration, output current, frequency, and haptic motor. The bipolar probe facilitates a more localized and precise stimulation field compared to a monopolar probe. The subject device offers additional output current levels which allow users to further adjust the stimulation field to interface nerves of various sizes. Although the output frequency of the subject device is 4Hz higher, functionally there is no difference physiologically when using the subject device compared to the predicate device. The haptic motor is used to provide additional feedback to the user to communicate stimulation delivery and device status.

The underlying mechanism of operation of the subject device remains the same as the predicate device. The differences do not raise new questions regarding safety, or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Evala Nerve Stimulator was evaluated with recognized consensus standards for EMC, electrical, thermal & mechanical safety including IEC 60601-1, IEC 60601-1-2, and applicable subparts of IEC 60601-2-10.

Testing was conducted to verify device requirements & performance (internal verification & validation testing including software verification & validation in accordance with IEC 62304), biocompatibility (ISO 10993-1, 10993-5, 10993-7, 10993-11, 10993-12, and 10993-23), usability and human factors (IEC 62366-1), labeling (ISO 15223-1 & IEC 60601-1), packaging (ISO 11607-1, ASTM D4332-22 & ASTM D4169-23e1), sterile barrier (ASTM F2096 & ASTM F88), sterility (ISO 14937, ISO 11737), and shelf life (ASTM F1980-21).

The above testing was conducted to demonstrate substantial equivalence between the predicate and the subject device.

Final Assessment of Substantial Equivalence
The Evala Nerve Stimulator and Checkpoint Head & Neck stimulator are identical in their intended use, principles of operation, fundamental technology, and general operation. The differences in the user interface and probe configuration do not raise new questions regarding safety and effectiveness. Therefore, the Evala Nerve Stimulator is substantially equivalent to the Checkpoint Head & Neck.