January 16, 2025

Nu Eyne Co., Ltd.
Dahee Kim
RA Manager
#608, 28, Digital-ro 30-gil, Guro-gu
Seoul, 08389
South Korea

Re: K243289
Trade/Device Name: ADDNOX (BPSPM1)
Regulation Number: 21 CFR 882.5898
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Attention Deficit Hyperactivity Disorder
Regulatory Class: Class II
Product Code: QGL
Dated: October 18, 2024
Received: October 18, 2024

Dear Dahee Kim:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ROBERT KANG -S

for Pamela Scott
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243289

Device Name

ADDNOX (BPSPM1)

Indications for Use *(Describe)*

The ADDNOX is indicated for the treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.
The ADDNOX is intended for patient treatment by prescription only and for use at home under the supervision of a caregiver during periods of sleep.

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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510(k) SUMMARY

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

Date: January 16, 2025

1. INFORMATION

1.1 Submitter Information

- Submitter Name: Nu Eyne Co., Ltd.
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- Telephone Number: +82-2-6953-8120
- Fax: +82-507-0330-8120
- Email: dahee.kim@nueyne.com

1.2 Contact Person

- Name: Dahee Kim (RA Manager / Nu Eyne Co., Ltd.)
- Address: #608, 28, Digital-ro 30-gil, Guro-gu, Seoul, 08389, Republic of Korea
- Telephone Number: +82-2-6953-8120
- Fax: +82-507-0330-8120
- E-mail: dahee.kim@nueyne.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: ADDNOX (Models: BPSPM1)

2.2 Common Name: Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder

2.3 Regulation Name: Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder

2.4 Product Code: QGL

2.5 Regulation Number: 21 CFR 882.5898

2.6 Regulatory Class: Class II

2.7 Classification Panel: Neurology

3. PREDICATE DEVICE

Predicate Device	
Manufacturer	Nu Eyne Co., Ltd.
Device Name (Trade Name)	SMILE
510(k) Number	K213629
Regulation Name	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder
Regulation Number	21 CFR 882.5898
Regulatory Class	Class II
Product Code	QGL

4. SUBJECT DEVICE DESCRIPTION

The ADDNOX is a transcutaneous electrical trigeminal nerve stimulator for Attention Deficit Hyperactivity Disorder. It is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead.

The ADDNOX is intended for patient treatment by prescription only and for use at home under the supervision of a caregiver during periods of sleep.

4.1 Principle of Operation

The ADDNOX treatment protocol is administered each night for 7-9 hours while the patient is sleeping. The device is designed to provide non-invasive electrical stimulation of the trigeminal nerve. The trigeminal nerve is the largest cranial nerve and has three major sensory divisions of the face, all of which are bilateral.

The trigeminal nerve provides a direct connection to multiple brain structures implicated in ADHD and other neurologic and neuropsychiatric disorders.

The ADDNOX treatment protocol has proven efficacy in alleviating ADHD symptoms with minimum risk.

5. INTENDED USE

ADDNOX is a device that stimulates the trigeminal nerves and is intended for ADHD.

6. INDICATIONS FOR USE

The ADDNOX is indicated for the treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.

The ADDNOX is intended for patient treatment by prescription only and for use at home under the supervision of a caregiver during periods of sleep.

7. SUBSTANTIAL EQUIVALENCE

Items	Subject Device	Predicate Device	Comparison Result
Manufacturer	Nu Eyne Co., Ltd.	Nu Eyne Co., Ltd.	Same
Device	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	Same
Trade/Device Name	ADDNOX	SMILE	Different
510(k) Number	K243289	K213629	Different
Regulation Number	21 CFR 882.5898	21 CFR 882.5898	Same
Regulation Description	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder	Same
Regulatory Class	Class II	Class II	Same
Product Code	QGL	QGL	Same
Intended Use	ADDNOX is a device that stimulates the trigeminal nerves and is intended for ADHD.	SMILE is the device that stimulates nerves and is intended for ADHD.	Same

Items	Subject Device	Predicate Device	Comparison Result
Definition	A transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead.	A transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead.	Same
Review Panel	Neurology	Neurology	Same
Physical State	Electrical stimulation unit with leads and cutaneous electrodes.	Electrical stimulation unit with leads and cutaneous electrodes.	Same
Technical Method	Applies an electrical current through electrodes on patient's skin.	Applies an electrical current through electrodes on patient's skin.	Same
Target Area	Trigeminal nerve	Trigeminal nerve	Same
Indications for Use	The ADDNOX is indicated for the treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The ADDNOX is intended for patient treatment by prescription only and for use at home under the supervision of a caregiver during periods of sleep.	The SMILE external Trigeminal Nerve Stimulation (eTNS) System is indicated for treatment of pediatric Attention Deficit Hyperactivity Disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is to be used for patient treatment by prescription only and is intended to be used in the home under	Same

Items		Subject Device	Predicate Device	Comparison Result
			the supervision of a caregiver during periods of sleep.	
Power Source		Rechargeable battery	Rechargeable battery	Same
S/W provided		Yes	Yes	Same
Patient Override Control Method		On/Off button	On/Off button	Same
Indicator Display: Unit Functioning		Yes	Yes	Same
Low Battery Indicator		Yes	Yes	Same
Standards		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 62366-1 IEC 62304 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 62366-1 IEC 62304 ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Device	**Timer Setting**	Yes	Yes	Same
	Weight	24.6 g	20.71 g	Different
	Dimension	45.00 mm x 44.00 mm x 18.80 mm	60.00 mm x 44.00 mm x 17.60 mm	Different
	Expected Service Life	3 years	1.5 years	Different
	Electrical Protection	Type BF	Type BF	Same

Items		Subject Device	Predicate Device	Comparison Result
Battery	**Battery Type**	Li-ion Polymer Battery	Lithium ion Battery	Same
	Expected Service Life	500 cycles of complete charge-discharge	300 cycles of complete charge-discharge	Different
	Maximum Input Voltage (Charging Method)	5.25 Vdc (Charging Cradle)	5.25 Vdc (USB Connector of the Device)	Different
Electrode	**Dimension**	78.00 mm (W) x 32.86 mm (H)	90.00 mm (W) x 31.90 mm (H)	Different
	Maximum Current Density (uA/cm2, r.m.s.)	1.34	1.41	Different
	Maximum Average Power Density (uW/cm2)	24.06	25.38	Different
Mobile Application		Yes	No	Different
Wireless Communication		Yes	No	Different
Materials				
Device Housing Material		Plastic ABS	Plastic ABS	Same
Technical specifications				
Waveform		Symmetrical square wave	Symmetrical square wave	Same
Maximum Output Current		10 mA	10 mA	Same
Maximum Output Voltage		5 V	5 V	Same
Pulse Duration		250 µS	250 µS	Same
Frequency		120 Hz	120 Hz	Same

Items	Subject Device	Predicate Device	Comparison Result
Stimulation Modulation Specifications (Cycling, Hours of Use)	30 Sec ON, 1 Sec Ramp Down / 30 sec OFF, 1 Sec Ramp Up Steady 7-9 hours	30 Sec ON, 1 Sec Ramp Down / 30 sec OFF, 1 Sec Ramp Up Steady 8 hours	Same

7.1 Differences between Subject Device and Predicated Device

1) Although the appearance and the charging method of the device differ between the subject device and the predicate device, the safety and performance tests according to IEC 60601-1 and IEC 60601-1-2 have demonstrated that this difference does not affect the safety and effectiveness of the subject device.

2) Although the expected service life differs between the subject device and the predicate device, the lifetime study activity has demonstrated that this difference does not affect the safety and effectiveness of the subject device.

3) Although the electrode differs between the subject device and the predicate device, the safety and performance tests according to IEC 60601-1, IEC 60601-2-10, bench testing standards, and ISO 10993 Series have demonstrated that this difference does not affect the safety and effectiveness of the subject device.

4) Although the features of the mobile application and wireless communication differ between subject device and the predicate device, the EMC test, the performance test under wireless communication, and the cyber security risk management activity have demonstrated that this difference does not affect the safety and effectiveness of the subject device.

8. NON-CLINICAL DATA

8.1 Safety Test

1) Biocompatibility

The biocompatibility tests were performed to protect patients from undue risks arising from biological hazards associated with the materials of manufacture and the final device. These tests were conducted in accordance with the following standards and FDA Guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

No.	Test Items	Standards
1	Cytotoxicity	ISO 10993-5:2009
2	Sensitization	ISO 10993-10:2010
3	Intracutaneous Reactivity Test	ISO 10993-10:2010

2) Electrical Safety and EMC

The electrical safety tests were performed to protect patients from undue risks arising from any hazards associated with the final device. These tests were conducted in accordance with the following standards.

No.	Test Items	Standards
1	General requirement for basic safety and essential performance	- IEC 60601-1:2005/A2:2020 (ANSI/AAMI ES60601-1:2005+A2:2021)
2	General requirement for safety - Electromagnetic disturbances	- IEC 60601-1-2:2014/A1:2020
3	General requirement for safety - Medical electrical equipment used in the home healthcare environment	- IEC 60601-1-11:2015/A1:2020 and - FDA Guidance (“Design Considerations for Devices Intended for Home Use”)
4	Particular requirement for safety – Nerve and muscle stimulators	- IEC 60601-2-10:2012/A1:2016

8.2 Performance Test

The following tests were performed to assess the effectiveness of the device's performance. These tests were conducted in accordance with the following standards.

No.	Test Items	Standards
1	Performance Test	- Manufacturer’s own standards
2	wireless communication test	- Manufacturer’s own standards
3	Lifetime study	- Manufacturer’s own standards

8.3 Software

The following test was performed to assess the effectiveness of the device's software. The test was performed in accordance with the following standards.

No.	Test Items	Standards
1	General requirement for safety - Programmable electrical medical systems (PEMS)	- IEC 62304:2006/A1:2015 - FDA Guidance ("Content of Premarket Submissions for Device Software Functions")

9. CLINICAL TESTING

No clinical testing was performed on the device.

10. CONCLUSION

When comparing substantial equivalence between the subject device and the predicate device, similarities exist in various aspects, including general information, technical details, and material details. Although some differences exist, the safety and performance test reports support the safety and effectiveness of the subject device. Therefore, we conclude that the subject device is substantially equivalent to the predicate device.