February 12, 2023

Nu Eyne Co., Ltd.
Sung jin Jung
Manager
#608, 28, Digital-ro 30-gil, Guro-gu
Seoul, 08389
Korea, South

Re: K213629
Trade/Device Name: Smile
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: January 10, 2023
Received: January 13, 2023

Dear Dong Lee:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Pamela D. Scott -S

Pamela D. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213629

Device Name
SMILE (Model: NUEYNE P022)

Indications for Use *(Describe)*
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 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.

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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 10, 2023

1. INFORMATION

1.1 Submitter Information

- Submitter Name: 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: +82-303-3447-0017
- Email: sungjin.jung@nueyne.com

1.2 Contact Person

- Name: Sung jin Jung (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: +82-303-3447-0017
- E-mail: sungjin.jung@nueyne.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: SMILE (Models: NUEYNE P022)

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

2.3 Classification Name: Transcutaneous Electrical Nerve Stimulator For Attention Deficit Hyperactivity Disorder

2.4 Product Code: QGL

2.5 Classification Regulation: 21 CFR 882.5898

2.6 Device Class: Class II (Special Controls)

2.7 Classification Panel: Neurology

Predicate Device	
Manufacturer	NeuroSigma, Inc.
Device Name (Trade Name)	Monarch eTNS System
De Novo Number	DEN180041

4. SUBJECT DEVICE DESCRIPTION

Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder. 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.

4.1 Device Identification

Component	**Description**
Instruction Manual	Instruction for Use
SMILE Device	Main Body
Cable	Charging Cable

4.2 Device Characteristics

Trade Name	SMILE (Models: NUEYNE P022)	
Classification Name	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder	
Common Name	Transcutaneous Electrical Nerve Stimulator For ADHD	
Classification Regulation	21 CFR 882.5898	
Regulation Description	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	
Device Class	Class II (Special Control)	
Panel	Neurology	
Product Code	QGL	
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.	
Physical State	Electrical stimulation unit with leads and cutaneous electrodes	
Technical Method	Applies an electrical current through electrodes on patient's skin	
Target Area	Trigeminal nerve	
Software	**Software Name**	Nueyne_SMILE
	Software Version	1.00
	Level-of Concern	Class B (Moderate Level)

The SMILE is not related to biologics, drugs, coatings, additives, single-use, and sterile.

4.3 Environment of Use

The device is to be used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep.

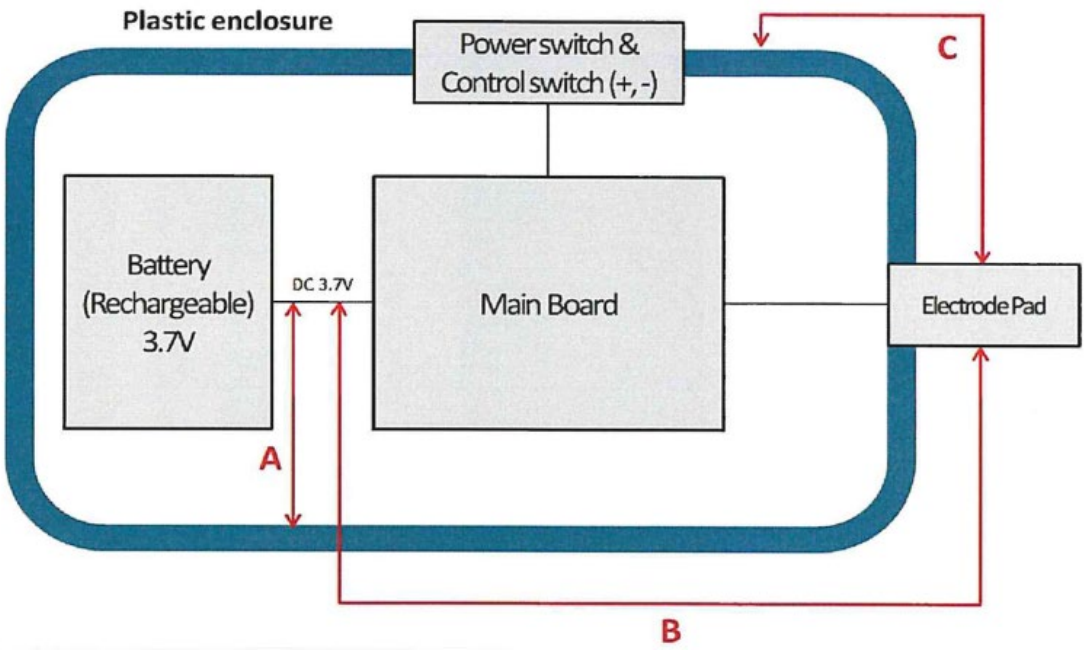
4.4 Description of the Device

(1) Explanation of how the device works/principle of operation

The SMILE eTNS System treatment protocol is administered each night while the patient is sleeping, for 7-9 hours. 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.

(2) Mechanism of action



(3) Any necessary feature to determine SE or device performance

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.

4.5 Materials of Use

The device is manufactured using the materials listed below. The device does not contain Phthalates and not incorporate medicinal substances, tissues, or blood products.

Product	Part	Technical data	Manufacturer
SMILE Device	Battery	TW342431-240mAh	SHENZEN TAIWOO BATTERY CO., LTD
	PCB	FR4, V-0	JDM CO LTD
	LED plastic	LUPOY PC, V-2	LG Chem
	Enclosure	ABS, V-0	LG Chem

We design the enclosure material of SMILE with Acrylonitrile butadiene styrene (ABS).

4.6 Key Performance Specifications/Characteristics of the Device

(1) SMILE device (TPD-PS02)

Classification	Protection against electric shock: Internally powered ME Equipment
	Applied part: Type BF
Dimensions (WxHxD)	60.00mm x 44.00mm x 17.60mm
Weight	20.71g
Power source	Rechargeable battery
Maximum output current	10mA
Lifetime	1.5 years
Operating condition	Temperature: 10°C ~ 40°C Relative humidity: 5% ~ 85 % Pressure: 700hPa ~ 1060hPa
Storage condition	Temperature: -10°C ~ 45°C Relative humidity: 5% ~ 85 % Pressure: 500hPa ~ 1060hPa

(2) Cable (CB-02)

Dimensions (Length)	1000mm
Current Rating	2A
Voltage Rating	250V

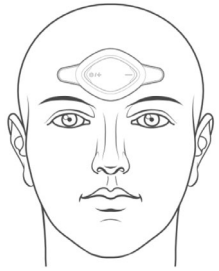
5. INTENDED USE

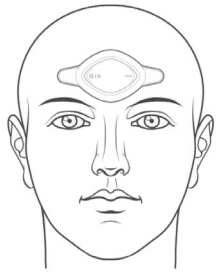
SMILE is a prescription device that stimulates nerves transcutaneously through electrodes placed on the forehead and is intended for pediatric ADHD.

6. SUBSTANTIAL EQUIVALENCE

Items	Subject Device	Predicate Device	Comparison Result
Manufacturer	Nu Eyne Co., Ltd.	NeuroSigma, Inc.	Different
Device	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	Same
Trade/Device Name	SMILE	Monarch eTNS System	Different
510(k)/Denovo Number	K213629	DEN180041	Different
Regulation Number	21 CFR 882.5898	21 CFR 882.5898	Same
Regulation Description	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactive Disorder	Same
Regulatory Class	Class II	Class II	Same
Product Code	QGL	QGL	Same
Intended Use	SMILE is the device that stimulates nerves and is intended for ADHD	Monarch eTNS System is Transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder.	Same
Definition	A transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously	A transcutaneous electrical nerve stimulator for Attention Deficit Hyperactivity Disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously	Same

	through electrodes placed on the forehead.	through electrodes placed on the forehead.	
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 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 the supervision of a caregiver during periods of sleep.	The Monarch 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 the supervision of a caregiver during periods of sleep.	Same

Picture			Different
Power Source	Rechargeable battery	Rechargeable battery	Same
Computerized	Yes	Yes	Same
S/W provided	MODERATE level of concern	MODERATE level of concern	Same
Max output current	10mA	10mA	Same
Patient Override Control Method	On/Off button	On/Off button	Same
Max Leakage Current	None (battery operated)	None (battery operated)	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	Same

		ISO 10993-5 ISO 10993-10	
Picture			Different
Power Source	Rechargeable battery	Rechargeable battery	Same
Computerized	Yes	Yes	Same
S/W provided	MODERATE level of concern	MODERATE level of concern	Same
Max output current	10mA	10mA	Same
Patient Override Control Method	On/Off button	On/Off button	Same
Max Leakage Current	None (battery operated)	None (battery operated)	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	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 62366-1 IEC 62304	Same

		ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	
Device	**Timer Setting**	Yes	Yes	Same
	Weight	20.71g	145 g (without battery)	Different
	Dimensions	60.00mm x 44.00mm x 17.60mm	69mm x 115mm x 27mm	Different
	Expected Service Life	1.5 years	5 years	Different
	Electrical Protection	Type BF	Type BF	Same
Battery	**Battery Type**	Lithium ion Battery	Lithium ion Battery	Same
	Expected Service Life	300 cycles of complete charge-discharge	300 charges per battery (10 months each)	Same
	Maximum input voltage (USB connector)	5.25 Vdc	5.36 Vdc	Different
Material				
Device housing materials		Plastic ABS	Plastic ABS	Same
Stimulation Characteristics				
Maximum charge per phase		2.5 uC (Max 10 mA)	2.5 uC	Same
Net Charge per pulse		0	0	Same
Peak and peak-to-peak current Peak voltage		± 10 mA	± 10 mA	Same
Phase duration		250 us	250 us	Same

Maximum average power density	20 uW/cm^2	7.5 mW/cm^2	Different Larger surface areamakes power density smaller
Maximum average current density	66.6 uA/cm^2	1.4 mA.cm^2	Different Larger surface area makes current density smaller
Skin contact surface area of the stimulating electrode	9 cm^2	7.1 cm^2	Different
And include the stimulation modulation specifications (Ramp up, Ramp down, on, and off and times for ramp up, ramp down, on, and off.	30 Sec ON, 1 Sec Ramp Down / 30 sec OFF, 1 Sec Ramp Up Steady 8 hours	30 Sec ON: 1 Sec Ramp Down: 30 Sec OFF: 1 Sec Ramp Up Steady 7-9 hours	Samet

7. NON-CLINICAL DATA

7.1 Electrical Safety and EMC Test

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

No.	Test Items	Standards
1	General requirement for basic safety and essential performance	- IEC 60601-1:2005/A1: 2012 (AAMI/ANSI ES 60601-1: 2005/A1: 2012)
2	General requirement for safety - Electromagnetic disturbances	- IEC 60601-1-2:2014
3	General requirement for safety - Medical electrical equipment used in the home healthcare environment	- IEC 60601-1-11:2015 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/Amd1:2016

7.2 Performance Test

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

No.	Test Items	Standards
1	Particular requirement for safety – Nerve and muscle stimulators	- IEC 60601-2-10:2012/Amd1:2016
2	Technical Test	- IEC 60601-2-10:2012/Amd1:2016

7.3 Usability V&V

The following tests were performed to assess effectiveness of usability of the device. The test was performed in accordance with following standards.

No.	Test Items	Standards and FDA Guidance documents
1	General requirement for safety – Usability	- IEC 60601-1-6:2013 - IEC 62366-1:2015 and - FDA Guidance ("Applying Human Factors and Usability Engineering to Medical Devices")

7.4 Software

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

No.	Test Items	Standards and FDA Guidance Documents
1	General requirement for safety - Programmable electrical medical systems (PEMS)	- IEC 62304:2006/AMD1:2015 - FDA Guidance ("Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices")

8. CONCLUSION

Under the comparing substantial equivalence between the subject device and the predicate device, there are the same points such as general information, some technical and material information. Although there are some differences, the safety and performance test reports are supported to the safety and effectiveness of the subject device.

In this regard, we conclude that the subject device is substantially equivalent to the predicate device.