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

November 6, 2024

Re: K242719
Trade/Device Name: ELEXIR 2.0 (ALLIVE3)
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache
Regulatory Class: Class II
Product Code: PCC
Dated: September 10, 2024
Received: September 10, 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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
Assistant Director
DHT5B: Division of Neuromodulation and Rehabilitation 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.

Submission Number *(if known)*

K242719

Device Name

ELEXIR 2.0 (ALLIVE3)

Indications for Use *(Describe)*

The ELEXIR 2.0 is indicated for the acute treatment of migraine (Acute mode, frequency 100 Hz) and the prophylactic treatment of episodic migraine (Prevention mode, frequency 60 Hz) in patients 18 years of age or older.

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 being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date: October 22, 2024

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: +82-507-0330-8120
- 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: ELEXIR 2.0 / Model: ALLIVE3

2.2 Common Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache

2.3 Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache

2.4 Product Code: PCC

2.5 Regulation Number: 21 CFR 882.5891

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)	ALLIVE2 (ELEXIR)
510(k) Number	K211380
Regulation Name	Transcutaneous Electrical Nerve Stimulator To Treat Headache
Regulation Number	21 CFR 882.5891
Regulatory Class	Class II
Product Code	PCC

4. SUBJECT DEVICE DESCRIPTION

The ELEXIR 2.0 is a transcutaneous electrical nerve stimulator (TENS) that is applied to the forehead using a self-adhesive electrode positioned over the upper branches of the trigeminal nerve bilaterally. It is intended to stimulate the upper branches of the trigeminal nerve in order to reduce the frequency of migraine attack. The ELEXIR 2.0 is indicated for the acute treatment of migraine and the prophylactic treatment of episodic migraine by applying 100 Hz (Acute mode) and 60 Hz (Prevention mode), low-frequency stimulation to the forehead area percutaneously to the trigeminal nerve.

5. INTENDED USE

The ELEXIR 2.0 is indicated for the acute treatment of migraine (Acute mode, frequency 100 Hz) and the prophylactic treatment of episodic migraine (Prevention mode, frequency 60 Hz) in patients 18 years of age or older.

6. SUBSTANTIAL EQUIVALENCE

Items	Subject Device	Predicate Device	Comparison Result
Manufacturer	Nu Eyne Co., Ltd.	Nu Eyne Co., Ltd.	Same
Trade/Device Name	ELEXIR 2.0 Model: ALLIVE3	ELEXIR/ALLIVE2	Different
510(k) Number	K242719	K211380	Different
Regulation Number	21 CFR 882.5891	21 CFR 882.5891	Same
Regulation Description	Transcutaneous electrical nerve stimulator to treat headache	Transcutaneous electrical nerve stimulator to treat headache	Same
Regulatory Class	Class II	Class II	Same
Product Code	PCC	PCC	Same
Definition	Used to apply an electrical current to a patient's cranium through electrodes placed on the skin.	Used to apply an electrical current to a patient's cranium through electrodes placed on the skin.	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	Afferent cranial nerves.	Afferent cranial nerves.	Same
Intended Use	The indications for use of the ELEXIR 2.0 are: - The acute treatment of migraine in patients 18 years of age or older.	The indications for use of the ELEXIR are: - The acute treatment of migraine in patients 18 years of age or older.	Same

Items		Subject Device	Predicate Device	Comparison Result
		- The prophylactic treatment of episodic migraine in patients 18 years of age or older.	- The prophylactic treatment of episodic migraine in patients 18 years of age or older.	
Power Source		1 rechargeable Lipo 3.7 V battery	1 rechargeable Lipo 3.7 V battery	Same
Channels		1	1	Same
S/W provided		2 fixed programs: - 1 fixed program for the acute treatment of migraine (Acute mode) - 1 fixed program for prophylactic treatment of episodic migraine (Prevention mode)	2 fixed programs: - 1 fixed program for the acute treatment of migraine attacks (Program 1) - 1 fixed program for prophylactic treatment of migraine (Program 2)	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
Device	**Timer Setting**	Yes	Yes	Same
	Weight	20.71 g	20.71 g	Same
	Dimensions	60.00 mm x 44.00 mm x 17.60 mm	60.00 mm x 44.00 mm x 17.60 mm	Same
	Expected Service Life	8 years	2 years	Different
Battery	**Battery Type**	Li-ion Polymer Battery	Lithium ion Battery	Same
	Expected Service Life	8 years	2 years	Different
	Maximum Input Voltage (USB connector)	5.25 Vdc	5.25 Vdc	Same

Items		Subject Device	Predicate Device	Comparison Result
Electrode	**Electrode Type**	Self-adhesive	Self-adhesive	Same
	Dimensions	78.00 mm (W) x 32.86 mm (H)	90 mm (W) x 31.9 mm (H)	Different
	Expected Service Life	20 times	20 times	Same
Mobile Application		Yes	No	Different
Wireless Communication		Yes	No	Different
Special Requirement b.3) in accordance with 21 CFR 882.5891				
Waveform		Biphasic	Biphasic	Same
Maximum Output Voltage (V)	**500 ohms**	8	8	Same
	2,000 ohms	32	32	Same
	10,000 ohms	65	65	Same
Maximum Output Current (mA)	**500 ohms**	16	16	Same
	2,000 ohms	16	16	Same
	10,000 ohms	6.5	6.5	Same
Pulse Duration (µS)		505	505	Same
Duration of the Primary (depolarizing) Phase (µS)		250	250	Same
Standby Duration between the Two Phases (µS)		5	5	Same
Net Charge (µC) per Pulse		0	0	Same
Maximum Current Density (mA/cm2, r.m.s.)	**500 ohms**	2.37	2.37	Same

Items		Subject Device		Predicate Device		Comparison Result
Maximum Average Power Density (W/cm2)	**500 ohms**	0.000017		0.000017		Same
Maximum Average Current (Average absolute value, mA)	**500 ohms**	0.48		0.48		Same
Wave Shape		Rectangular Full compensated Symmetrical		Rectangular Full compensated Symmetrical		Same
Modulation Option	**Amplitude**	0 to 16 mA Fixed		0 to 16 mA Fixed		Same
	Frequency	**Acute mode**	100 Hz fixed	**Program 1**	100 Hz fixed	Same
		Prevention mode	60 Hz fixed	**Program 2**	60 Hz fixed	
	Duration	250 µS		250 µS		Same
Ramp Modulation	**Ramp Up**	14 min.		14 min.		Same
	Ramp Down	1 min.		1 min.		Same
Steady Time		**Acute mode**	45 min.	**Program 1**	45 min.	Same
		Prevention mode	5 min.	**Program 2**	5 min.	
Session Duration		**Acute mode**	60 min.	**Program 1**	60 min.	Same
		Prevention mode	20 min.	**Program 2**	20 min.	
Amplitude Modulation		Amplitude is adjusted by the user.		Amplitude is adjusted by the user.		Same
Material						
Device Housing Materials		Plastic ABS		Plastic ABS		Same
Electrode Gel used		Hydrogel		Hydrogel		Same

6.1 Differences between Subject Device and Predicate Device

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

2) Although the dimension of the electrode differs between the subject device and the predicate device, the safety and performance tests according to IEC 60601-1 and IEC 60601-2-10 have demonstrated the electrode feature of the subject device, ensuring that this difference does not affect the safety and effectiveness of the subject device.

3) 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 the use of mobile application and wireless communication, ensuring that this difference does not affect the safety and effectiveness of the subject device.

7. NON-CLINICAL DATA

7.1 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+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/A1:2016

7.2 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	Particular requirement for safety – Nerve and muscle stimulators	- IEC 60601-2-10:2012/A1:2016
2	Technical Test	- IEC 60601-2-10:2012/A1:2016
3	Performance Test under wireless communication	- Manufacturer’s own standards

No.	Test Items	Standards
4	Lifetime study	- Manufacturer's own standards

7.3 Usability V&V

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

No.	Test Items	Standards
1	General requirement for safety – Usability	- IEC 60601-1-6:2010/A1:2013 - IEC 62366-1:2015 and - FDA Guidance ("Applying Human Factors and Usability Engineering to Medical Devices")

7.4 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")

8. 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.