July 30, 2021

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

Re: K211380
Trade/Device Name: Elexir
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous electrical nerve stimulator to treat headache
Regulatory Class: Class II
Product Code: PCC
Dated: April 28, 2021
Received: May 4, 2021

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,

Patrick Antkowiak
Assistant Director (Acting)
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)*
K211380

Device Name
ELEXIR (MODEL: ALLIVE2)

Indications for Use *(Describe)*
THE ELEXIR is indicated for the acute treatment of migraine (program 1) and the prophylactic treatment of episodic migraine (Program 2) in patients 18 years of age or older

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

[X] 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 requirements of 21 CFR Part 807.92.

Date: APRIL, 28, 2021

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: dongdeong.lee@nueyne.com

1.2 Contact Person

- Name: Dong Seong Lee (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: dongseong.lee@nueyne.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: ELEXIR (Model: ALLIVE2)

2.2 Common Name: Transcutaneous electrical nerve stimulator to treat headache

2.3 Classification Name: Stimulator, Nerve, Electrical, Transcutaneous, For Migraine

2.4 Product Code: PCC

2.5 Classification Regulation: 21CFR 882.5891

2.6 Device Class: Class II (Special Control)

2.7 Classification Panel: Neurology

3. PREDICATE DEVICE

Predicate Device	
Manufacturer	CEFALY Technology
Device Name (Trade Name)	CEFALY® Dual
510(k) Number	K173006

4. SUBJECT DEVICE DESCRIPTION

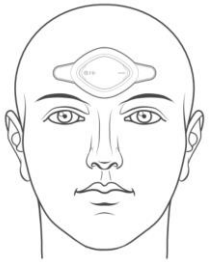
The ELEXIR device is a transcutaneous electrical nerve stimulator (TENS) that is applied to the forehead using a self-adhesive electrode positioned over the upper branches of the trigeminal verve bilaterally. It is intended to stimulate the upper branches of the trigeminal verve in order to reduce the frequency of migraine attack.

5. INTENDED USE

The ELEXIR is indicated for the acute treatment of migraine (program 1) and the prophylactic treatment of episodic migraine (program 2) in patients 18 years of age or older.

6. SUBSTANTIAL EQUIVALENCE

Items	Subject Device	Predicate Device	Comparison Result
Manufacturer	Nu Eyne Co., Ltd.	CEFALY Technology	Different
Device	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine	Same
Trade/Device Name	ELEXIR/ALLIVE2	CEFALY® Dual	Different
K Number	None	K173006	Different
Regulation Number	21CFR 882.5891	21CFR 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 are: - The acute treatment of migraine with or without aura in 18 years of age or older; - The prophylactic treatment of episodic migraine in patients 18 years of age or older.	The indications for use of the Cefaly® Dual are: - The acute treatment of migraine with or without aura in 18 years of age or older; - The prophylactic treatment of episodic migraine in patients 18 years of age or older.	Same
Picture			Different
Power Source	1rechargeable Lipo 3.7 V battery	1rechargeable Lipo 3.7 V battery	Same
Channels	1	1	Same
Computerized	Yes	Yes	Same
S/W provided	2 fixed program: - 1 fixed program for the acute treatment of migraine attacks (Program 1)	2 fixed program: - 1 fixed program for the acute treatment of migraine attacks (Program 1)	Same

		- 1 fixed program for prophylactic treatment of migraine (Program 2)	- 1 fixed program for prophylactic treatment of migraine (Program 2)	
Constant current		Yes	Yes	Same
Constant voltage		No	No	Same
Max output current		16mA	16mA	Same
Max output voltage (2kOhm)		32 Volts	32 Volts	Same
Patient Override Control Method		On/Off button	On/Off button	Same
Max Leakage Current		None (battery operated)	None (battery operated)	Same
Electrode		Self-adhesive	Self-adhesive	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	20.71g	12g	Different
	Dimensions	60.00mm x 44.00mm x 17.60mm	55mm x 35mm x 15mm	Different
	Expected Service Life	2 years	7 years	Different

	IP Classification		IP22	IP22	Same
	Electrical Protection		Type BF	Type BF	Same
Battery	**Battery Type**		Lithium ion Battery	Lithium ion Battery	Same
	Expected Service Life		2 years (75Cycles of complete discharge)	7 years (300Cylces of complete discharge)	Different
	Maximum input voltage (USB connector)		5.25 Vdc	5.25 Vdc	Same
Electrode	**Dimensions**		90mm (W) x 31.9mm (H)	94mm (W) x 30mm (H)	Different
	Expected Service Life		20 times	20 times	Same
Special Requirement b.3) in accordance with 21CFR 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	60	Same
Maximum output current (mA)	**500 ohms**		16	16	Same
	2,000 ohms		16	16	Same
	10,000 ohms		6.5	6	Same
Pulse duration (µS)			505	505	Same
Frequency		**Program 1**	100Hz fixed	**Program 1** 100Hz fixed	Same
		Program 2	60Hz fixed	**Program 2** 60Hz fixed	
Net charge (µC) per pulse			0	0	Same
Duration of the primary (depolarizing) phase			250	250	Same

(µS)						
Standby duration between the two phase (µS)		5		5		Same
Maximum current density (mA/cm2, r.m.s.)	**500 ohms**	2.37		2.37		Same
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
Other Technical Item						
Wave Shape		Rectangular Full compensated Symmetrical		Rectangular Full compensated Symmetrical		Same
Method		Same charge quantity on positive and negative impulse		Same charge quantity on positive and negative impulse		Same
Max phase amplitude		16mA with a load of a 4.7 µF capacitor parallel with 2.2K ohms resistance		16mA with a load of a 4.7 µF capacitor parallel with 2.2K ohms resistance		Same
Phase rise time		2 µS		2 µS		Same
Phase decay time		2 µS		2 µS		Same
Interphase interval		nil		nil		Same
Burst mode		No		No		Same
Maximum Phase Charge (µS) at 500 ohms		4		4		Same
Modulation option	**Amplitude**	0 to 16 mA Fixed		0 to 16 mA Fixed		Same
	Frequency	**Program 1**	100 Hz fixed	**Program 1**	100 Hz fixed	Same
		Program 2	60Hz fixed	**Program 2**	60Hz 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		**Program 1**	45 min	**Program 1**	45 min	Same
		Program 2	5 min	**Program 2**	5min	
Session Duration		**Program 1**	60 min	**Program 1**	60 min	Same
		Program 2	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 top layer		Polyethylene terephthalate		Polyurethane		Different
Electrode intermediate layer		Conductive silver carbon ink		Carbon with silver coating		Different
Electrode bottom layer		x		x		same
Central pin		N/A		N/A		Same
Metallic parts for magnetic attraction		Tinplate		Tinplate		Same

7. NON-CLINICAL DATA

7.1 Safety Test

1) Biocompatibility

The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were performed 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 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
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
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. CLINICAL DATA

Although clinical performance data are required to demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population on the special control according to clause b.6) of 21CFR882.5981, we consider that the subject device (ELEXIR) is not applied with clause b.6) of 21CFR882.5981.

Although there are not the clinical performance data of the subject device, we prepare the clinical evaluation report by using the collected clinical data of the predicate device.

In this evaluation report, the subject device is safe and effective as a treatment for headache in the indicated patient population.

The clinical evaluation was performed in accordance with following standards.

No.	Test Items	Standards
1	Clinical Evaluation	- MEDDEV 2.7.1. rev.4

9. 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.