June 11, 2024

Ybrain, Inc.
℅ Jonghyun Kim
CEO, GMS Consulting
#612, DE Riverwork Building B, 66, Cheongcho-ro, Deogyang-gu
Goyang-si, Gyeonggi-do 10543
Korea, South

Re: K232749
Trade/Device Name: Doopang
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous electrical nerve stimulator to treat headache
Regulatory Class: Class II
Product Code: PCC
Dated: May 24, 2024
Received: May 24, 2024

Dear Jonghyun 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.

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232749

Device Name

DOOPANG (YPS-301BD)

Indications for Use *(Describe)*

The DOOPANG(YPS-301BD) is indicated for:
- The acute treatment of migraine with or without aura in patients 18 years of age or older.
- The prophylactic treatment of episodic migraine 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) Summary

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

May 23, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Ybrain, Inc.
- Address: 228, 54, Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, Republic of Korea (zip code 13449)
- Contact Name: Kiwon, Lee/President
- Telephone No.: +82-70-4190-1899
- Email Address: ra@ybrain.com
- Registration No.: PCC

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

510(k) Number	K232749
Trade/Device/Model Name	DOOPANG/DOOPANG/YPS-301BD
Product Name	Transcutaneous Electrical Nerve Stimulator to Treat Headache
Device Classification Name	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation Number	21 CFR 882.5891
Classification Product Code	PCC
Device Class	Class II
510(k) Review Panel	Neurology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

Predicate Device

510(k) Number	K201895
Trade/Device/Model Name	Cefaly Dual
Product Name	Transcutaneous Electrical Nerve Stimulator to Treat Headache
Device Classification Name	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation Number	21 CFR 882.5891
Classification Product Code	PCC
Device Class	Class II
510(k) Review Panel	Neurology

These predicate devices have not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

This product is a small, portable product that uses the principle of transcutaneous nerve stimulation. By attaching an electrode to the forehead, it transmits electrical stimulation to the upper branch of the trigeminal nerve transdermally.

The electrode surface transmits electric current to the skin to generate action potentials on the nerves and adjusts the output mode (Program 1 and Program 2) to preventative treatment of episodic migraine(60Hz) and acute treatment of migraine(100Hz). Specially designed electrode of this product allows contact with the trigeminal nerve endings associated with migraine headaches. The electrodes give nerve stimulation to the orbital upper branch (V1) inside the forehead skin and transmit it to the trigeminal nervous system. This electrical stimulation is transmitted percutaneously through a bipolar adhesive electrode located on the forehead to preventative treatment of episodic migraine(60Hz) or acute treatment of migraine(100Hz).

6. Indications for use [21 CFR 807.92(a)(5)]

The DOOPANG(YPS-301BD) is indicated for:

- The acute treatment of migraine with or without aura in patients 18 years of age or older.
- The prophylactic treatment of episodic migraine in patients 18 years of age or older.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the DOOPANG(YPS-301BD) and the predicate device:

[Table 1. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	**Predicate Device**	**Note**
K Number	K232749	K201895	-
Manufacturer	Ybrain, Inc.	CEFALY Technology	-
Trade Name(Model Name)	DOOPANG(YPS-301BD)	Cefaly Dual	-
Product Name	Transcutaneous Electrical Nerve Stimulator to Treat Headache	Transcutaneous Electrical Nerve Stimulator to Treat Headache	-
Product Code	PCC	PCC	Same
Regulation Number	21 CFR 882.5891	21 CFR 882.5891	Same
Regulatory Class	II	II	Same
	Proposed Device	**Predicate Device**	**Note**
510(k) Review Panel	Neurology	Neurology	Same

Indications for Use	DOOPANG(YPS-301BD) is indicated for: - The acute treatment of migraine with or without aura in patients 18 years of age or older. - The prophylactic treatment of episodic migraine in patients 18 years of age or older.	The Cefaly® Dual is indicated for: - The acute treatment of migraine with or without aura in patients 18 years of age or older. - The prophylactic treatment of episodic migraine in patients 18 years of age or older.	Similar
Intended Population	Patients 18 years of age or older	Patients 18 years of age or older	Same
Intended Use Environment	Home & Healthcare settings	Home & Healthcare settings	Same
Power Source	A rechargeable 3.7V Lithium-Polymer Battery	1 rechargeable LiPo 3.7 V battery	Same
Channels	1	1	Same
Software provided	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)	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
Program 1: Max. output current Pulse width Pulse frequency Session duration	 16 mA 250 μs, fixed 100 Hz, fixed 61 minutes	 16 mA 250 μs, fixed 100 Hz, fixed 60 minutes	Similar
Program 2: Max. output current Pulse width Pulse frequency Session duration	 16 mA 250 μs, fixed 60 Hz, fixed 21 minutes	 16 mA 250 μs, fixed 60 Hz, fixed 20 minutes	Similar
Waveform	Biphasic, rectangular, symmetrical	Biphasic, rectangular, symmetrical	Same
Net charge (μC) per pulse	0	0	Same
Maximum output current (mA):	16 mA	16 mA	Same
Maximum current density (mA/cm2, r.m.s) at 500 ohms	2.32	2.37	Similar
Maximum average power density (W/cm2, r.m.s) at 500 ohms	0.000047	0.000047	Same

It is substantially equivalent to these devices in design, function, and intended use. The proposed device, DOOPANG(YPS-301BD) has been tested about electrical safety, EMC, and performance, and the software has been validated. Differences and Risks associated with that:

- There appears to be a slight difference in session duration between Program 1 and Program 2 for both the predicate device and the proposed device. However, this discrepancy is not

expected to pose any significant additional risk, as the variation is within a minute or less.

- The Maximum current density (mA/cm2, r.m.s) at 500 ohms of the proposed device is 2.32, while the predicate device has a value of 2.37. Although there is a slight difference, it can be argued that the performance of the proposed device is less risky because it falls within the performance range of the predicate device.

There are no significant differences between the DOOPANG(YPS-301BD) and the predicate device that would adversely affect the product's use according to the test results. Therefore, these differences do not raise different questions of safety and effectiveness than the predicate.

8. Non-Clinical Test summary

The DOOPANG(YPS-301BD) complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The DOOPANG(YPS-301BD) complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60601-1	AAMI/IEC	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)	ES60601-1: 2005(R)2012 and A1:2012	2014
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02	2016
60601-1-6	IEC	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	60601-1-6 Edition 3.0 2012-07	2012
60601-1-11	IEC	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	60601-1-11 Edition 2.0 2015-01	2016
60601-2-10	IEC	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	60601-2-10 Edition 2.1 2016-04	2018
62366-1	IEC	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	2020

2) Software Validation

The DOOPANG(YPS-301BD) contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices, on May 11, 2005

3) Biocompatibility

- ISO 10993-1 and series, Biological evaluation of medical devices

4) Cybersecurity

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, on October2, 2014

5) Label

- CFR Part 801

6) Performance

- Performance Evaluation Test
- Real Time Stability Test

7) Usability

- Usability Test (IEC 62366-1:2015+AMD1:2020 CSV)

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the proposed device and the predicate device, K201895 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the DOOPANG(YPS-301BD) is substantially equivalent in safety and effectiveness to the predicate device as described herein.