June 3, 2024

Soterix Medical, Inc.
Abhishek Datta
CEO/CTO
1480 U.S. Highway 9 North
Suite 204
Woodbridge, New Jersey 07095

Re: K233751
Trade/Device Name: Milieve (YPS-301BD)
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache
Regulatory Class: Class II
Product Code: PCC
Dated: May 3, 2024
Received: May 3, 2024

Dear Dr. Abhishek Datta:

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)*

K233751

Device Name

Milieve (YPS-301BD)

Indications for Use *(Describe)*

The Milieve 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.

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510(k) SUMMARY

Submission Date: November 17th, 2023

Submitter Information:

Company Name: Soterix Medical, Inc.
1480 US Highway 9 North
Suite 204
Woodbridge, NJ 07095

Contact Person(s) : Danielle Dadona (Regulatory Affairs Specialist)
Abhishek Datta (CEO / CTO)
Phone: 888-990-8327
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Device Information:

Trade Name: Milieve (YPS-301BD)

Common Name: Milieve

Classification Name: PCC - Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
(21 CFR 882.5891)

Device Class: Class II

Predicate Device: Cefaly Dual (K201895)
CEFALY Technology
Class II

Device Description: The Milieve device is a transcutaneous electrical nerve stimulator (TENS) developed for the acute treatment of migraine and the prophylactic treatment of episodic migraine. The device is placed on the patient's forehead to stimulate the upper branch of the trigeminal nerve. It is harmless to the human body. The Milieve device is indicated for OTC use.

There are two treatment programs: ACUTE and PREVENT. The ACUTE treatment program is intended for treatment during migraine attack at the onset of a migraine. The PREVENT treatment program is meant for daily preventative treatment.

The Mileve device comprises a plastic external casing and electrical components. It is operated by an internal rechargeable battery.

Intended Use/Indications:

The indications for use of the Milieve device for **over-the-counter** use are:

- 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.

Technological Comparison:

The Milieve uses the same technological principle as the predicate device to accomplish its intended use, namely the stimulation of the upper branch of the trigeminal nerve to treat and prevent migraine. In conjunction with the Cefaly Dual approved for the treatment and prevention of migraine Milieve's intended use is similar to that of the predicate. All output specifications of the subject device are either identical or substantially equivalent to the predicate device.

Basis for Equivalence:

- **Performance Testing:** Bench testing demonstrated that the performance parameters of the Milieve device are substantially equivalent to that of the predicate device. The subject device is compliant to the same international standards as the legally marketed predicate device. Further, software verification and validation and risk management demonstrate that Milieve is substantially equivalent to the predicate device.

- **Labeling:** The labeling of the Milieve device is substantially equivalent to that of the predicate device.

Conclusions from Testing:

The Milieve device is substantially equivalent to the predicate device. The Milieve device is identical to its predicate device in intended use. Bench testing supports the conclusion that the performance parameters of the Milieve device is substantially equivalent to the predicate devices, and any differences between the devices do not pose new questions of safety and effectiveness.

Parameter	Milieve	Cefaly Dual (Predicate Device)	Comparison
510(k)	Proposed Device	K201895	--
Device Name and Model	Milieve (YPS-301BD)	Cefaly Dual	--
Manufacturer	Ybrain Inc.	CEFALY Technology	--
Indications For Use	The indications for use of the Milieve for an over-the-counter use are: - 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 indications for use of the Cefaly Dual for an over-the-counter use are: - 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.	**Identical**
Classification Name	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine	**Identical**
Product Code	PCC	PCC	**Identical**
Regulatory Class	Class II	Class II	**Identical**
Classification Number	Sec 882.5891	Sec 882.5891	**Identical**
Contraindications For Use	Subjects with implanted metallic or electronic devices in the head. Subjects suffering from pain of unknown origin. Subjects who have a cardiac pacemaker or implanted or wearable defibrillator. This may cause interference with pacing, electric shock, or death.	Subjects with implanted metallic or electronic devices in the head. Subjects suffering from pain of unknown origin. Subjects who have a cardiac pacemaker or implanted or wearable defibrillator. This may cause interference with pacing, electric shock, or death.	**Identical**

Parameter	Milieve	Cefaly Dual (Predicate Device)	Comparison
Power Source	Rechargeable 3.7V LiPo Battery	Rechargeable 3.7V LiPo Battery	**Identical**
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)	**Identical**
Program 1: Max. output current Pulse width Pulse frequency Session duration	 16 mA 250 µs fixed 100 Hz fixed 60 minutes	 16 mA 250 µs fixed 100 Hz fixed 60 minutes	**Identical**
Program 2: Max. output current Pulse width Pulse frequency Session duration	16 mA 250 µs fixed 60 Hz fixed 20 minutes	16 mA 250 µs fixed 60 Hz fixed 20 minutes	**Identical**
Waveform	Biphasic, symmetric, rectangular current impulses with zero electrical mean	Biphasic, symmetric, rectangular current impulses with zero electrical mean	**Identical**
Phase Duration (or Pulse width)	250 µs	250 µs	**Identical**
Inter Phase Interval	5 µs	5 µs	**Identical**
Maximum Current Intensity (±10%) @500Ω @2000Ω @10000Ω	 16 mA 16 mA 6 mA	 16 mA 16 mA 6 mA	**Identical**
Maximum average current @500Ω	0.48 mA	0.48 mA	**Identical**
Maximum output voltage (±10%)			**Identical**

Parameter	Milieve	Cefaly Dual (Predicate Device)	Comparison
@500Ω @2000Ω @10000Ω	8 V 32 V 60 V	8 V 32 V 60 V	
Ramp up Time	14 min	14 min	**Identical**
Steady Time	6 min	6 min	**Identical**
Ramp down Time	60 s	45 s	**SE** Note 1
Maximum Phase Charge @500 Ω	4 µC	4 µC	**Identical**
Net Charge per Pulse	0	0	**Identical**
Maximum Current Density @500 Ω	2.37 mA/cm^2	2.37 mA/cm^2	**Identical**
Maximum Average Power Density @500 Ω	0.000047 W/cm^2	0.000047 W/cm^2	**Identical**
Dimensions	44.05 mm x 38.98 mm x 14.5 mm	55 mm x 40 mm x 15 mm	**SE** Note 2
Weight	21 g	12 g	**SE** Note 3
Electrode	Self-adhesive with 2 conductive zones	Self-adhesive with 2 conductive zones	**Identical**
Device output ports	2 magnets for connection with electrode	2 magnets for connection with electrode	**Identical**

Note 1:
The subject device has a slightly longer ramp down time. This longer ramp time helps with subject comfort. This difference will not raise new questions of efficacy as the therapeutic session times (20 min and 60 min) are identical.

Note 2:
The dimension of the subject device is slightly different from the predicate device. This minor difference will however not raise any new safety and effectiveness issues.

Note 3:
The weight of the subject device is slightly more than the predicate device. This minor weight increase has not impacted the ability to hold device and electrode reliably on the forehead in the in-house tests conducted and the human factors validation study. It is therefore expected to not raise any new safety and effectiveness issues.