



April 16, 2026

Hinge Health, Inc.  
Roop Pandher  
Staff Engineer, Regulatory and Quality  
455 Market St., Suite 700  
San Francisco, California 94105

Re: K254216  
Trade/Device Name: Enso for Migraine  
Regulation Number: 21 CFR 882.5891  
Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache  
Regulatory Class: Class II  
Product Code: PCC  
Dated: December 24, 2025  
Received: December 29, 2025

Dear Roop Pandher:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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](mailto: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  
Physical Medicine Devices

OHT5: Office of Neurological and  
Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K254216

Device Name

Enso for Migraine

Indications for Use (Describe)

Enso for Migraine is indicated for patients 18 years of age or older for acute treatment of migraine with or without aura and preventative treatment of migraine.

Enso for Migraine is for patients diagnosed with migraine by a physician.

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

The following information is provided in accordance with 21 CFR 807.92.

<b>510(k) Submitter</b>	Hinge Health Inc. 455 Market Street Suite 700 San Francisco, CA 94105
<b>Contact Person</b>	Roopkamal Pandher Staff Engineer Regulatory & Quality Hinge Health Email: <a href="mailto:roopkamal.pandher@hingehealth.com">roopkamal.pandher@hingehealth.com</a> Tel: +1 (855) 902-2777
<b>Date Prepared</b>	April 16, 2026
<b>Common Name</b>	Transcutaneous electrical nerve stimulator to treat headache
<b>Device Trade Name</b>	Enso for Migraine
<b>Classification</b>	Class II
<b>Regulation</b>	21 CFR 882.5891 Transcutaneous electrical nerve stimulator to treat headache
<b>Product Code</b>	PCC
<b>Panel</b>	Neurology
<b>Proposed Predicate Device</b>	K234029 CEFALY Connected – OTC 21 CFR 882.5891, PCC, Class II

## Device Description:

The Enso for Migraine is an over-the-counter medical device that is intended to be used by patients 18 years of age or older for the acute treatment of migraine with or without aura and the preventative treatment of migraine. The Enso for Migraine is a wearable, app-controlled system that can be used to excite nerves in the head via transcutaneous electrical nerve stimulation (“TENS”) to create a neuromodulation effect that reduces the severity and frequency of migraines.

The Enso for Migraine system includes the following physical components: the Enso Device (the TENS unit), reusable and disposable self-adhesive hydrogel pads (“gel pads”), a charging dock, cable, and AC adapter for recharging, disposable skin wipes, a paper copy of the user manual and quick start guide, and a bag for storage between sessions. The Enso Device attaches by magnets to a

cradle on the gel pad, which is adhered to the skin for a treatment session. The Enso Device delivers transcutaneous electrical stimulation via electrodes integrated into the gel pad.

The Enso Device is controlled wirelessly using the Hinge Health mobile application (“App”), which has been downloaded by the user to a compatible mobile device. The App allows the user to administer the TENS treatment session and control treatment settings.

**Intended Use:**

The predicate and subject devices share an intended use, namely the application of an electrical current through electrodes placed on the skin to treat headache in adults.

**Table 1.** Indications for Use comparison

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine
Indications for Use	Cefaly Connected - OTC is indicated for: 1. Acute treatment of migraine with or without aura in patients 18 years of age or older 2. Preventative treatment of migraine in patients 18 years of age or older	Enso for Migraine is indicated in patients 18 years of age or older for the acute treatment of migraine with or without aura and the preventative treatment of migraine.  Enso for Migraine is for patients diagnosed with migraine by a physician.

Although the formatting differs slightly, the language and meaning are the same and the subject statement conveys the same intended use as the predicate.

**Technological Characteristics:**

The table below provides a comparison of the technological characteristics of the predicate and subject devices. Where there are differences, a discussion of why they do not raise issues of safety and effectiveness is included below the table under the referenced header.

**Table 2.** Comparison of technological characteristics

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
Indications for Use	Acute and preventative treatment of migraine, ≥18 yrs	Acute and preventative treatment of migraine, ≥18 yrs	Same	Equivalent Indications

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
Operating Principle	TENS via hydrogel pad/electrode to forehead	TENS via hydrogel pad/electrode to forehead	Same	Not Applicable
Placement	Center of forehead	Center of forehead	Same	Not Applicable
TENS System Components	Neurostimulator, gel pad, charging dock/cable, mobile app	Neurostimulator, gel pad, charging dock/cable, mobile app, skin wipes	Different	Subject device includes cosmetic skin wipes for convenience (no impact on safety/effectiveness)
Neurostimulator Dimensions/Weight	66×47×17 mm / 25g	42×42×11 mm / 13.5g	Different	Smaller form factor increases portability, no functional impact
Battery	3.7V rechargeable LiPo	3.85V rechargeable LiPo	Different	No functional impact; compatible with circuitry; similar battery life
Controls/ User Interface	On-device multi-function button and app	Functions via mobile app, single on-device button	Different	Predicate: Treatment selection via device/app; Subject: All selection via app. Both allow safe treatment stop. No safety/effectiveness impact.

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
Visual/Audio Indicators	Visual indicators plus audio signals	Visual indicators only (via device + app)	Different	Audio indicator absent in subject; not necessary due to app-based controls. No impact.
Electrode (Gel Pad) Size/Shape	94×20 mm	86×49 mm	Different	Subject is larger; ensures similar current delivery, lowers current density. Safe and effective.
Electrode Material	Acrylic hydrogel	Acrylic hydrogel	Same	Not Applicable
Bluetooth Connectivity	Yes	Yes	Same	Not Applicable
Channels	1	1	Same	Not Applicable
Output modes	<ul style="list-style-type: none"> <li>Preventative</li> <li>Acute</li> </ul>	<ul style="list-style-type: none"> <li>Preventative</li> <li>Acute (called 'Calm')</li> </ul>	Same	Not Applicable
Max Output Current (mA)	16 (at 500/2000 Ω), 6 (10,000 Ω)	15 (at 500/2000 Ω), 7 (10,000 Ω)	Slightly Different	1 mA difference, not clinically significant. Variability in patient use outweighs difference.
Max Output Voltage (V)	8 (500 Ω), 32 (2000 Ω), 60 (10,000 Ω)	8 (500Ω), 30 (2000Ω), 73 (10,000Ω)	Slightly Different	Reflects output specs and pad design. No safety concern.

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
Waveform	Biphasic, symmetric, rectangular, fully compensated	Biphasic, asymmetric, rectangular, fully compensated	Different (Recovery phase)	Both achieve zero net charge/pulse. No impact; both used in TENS.
Maximum current density (mA/cm <sup>2</sup> , r.m.s.) at 500 ohms	2.37	1.09	Different (Lower in subject)	Lower density due to larger pad; reduces risk of hotspots.
App Features	Treatment session control, intensity adjustment, logs	Treatment session control, intensity adjustment, logs	Same	Not Applicable
Biocompatibility /Electrical Safety	Compliant (per predicate K234029)	Compliant (IEC 60601, ISO 10993)	Same	Both meet applicable standards (per performance data)
Net charge (μC) per pulse	0	0	Same	Not Applicable
Maximum Phase Charge (μC) at 500 ohms	4	4	Same	Not Applicable
Type of impedance monitoring system	Electrical	Electrical	Same	Not Applicable
PREVENTATIVE Amplitude (mA)	0 - 16	0 - 15	Different	1 mA difference, not clinically significant.
PREVENTATIVE Pulse active phase width (μs)	250	249	Different	Minor differences (1 μs) not clinically relevant.

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
PREVENTATIVE Pulse frequency (Hz)	60	60	Same	Not Applicable
PREVENTATIVE Pulse duration ( $\mu$ s)	505	516	Different	Minor difference in recovery phase duration not clinically significant.
PREVENTATIVE Session duration (min)	20	20	Same	Not Applicable
PREVENTATIVE Maximum average current (average absolute value, mA) at 500 ohms	0.48	0.31	Different	Difference arises from the subject device using passive rather than active recovery - no clinical impact, given that primary active phases are comparable.
PREVENTATIVE Maximum average power density (W/cm <sup>2</sup> ) at 500 ohms	0.000017	0.00020 (*0.000011)	Different	Difference arises from the subject device using passive rather than active recovery - no clinical impact, given that primary active phases are comparable.
ACUTE Amplitude (mA)	0 - 16	0 - 15	Different	1 mA difference, not clinically significant.

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
ACUTE Pulse active phase width ( $\mu$ s)	250	249	Different	Minor differences (1 $\mu$ s) not clinically relevant.
ACUTE Pulse frequency (Hz)	100	101	Different	Minor differences (1 Hz) not clinically relevant.
ACUTE Pulse duration ( $\mu$ s)	505	510	Different	Minor difference in recovery phase duration not clinically significant.
ACUTE Session duration (min)	60	60	Same	Not Applicable
ACUTE Maximum average current (average absolute value, mA) at 500 ohms	0.8	0.51	Different	Difference arises from the subject device using passive rather than active recovery - no clinical impact, given that primary active phases are comparable.

	Predicate Device K234029 Cefaly Connected - OTC	Subject Device Enso for Migraine	Comparison	Impact
ACUTE Maximum average power density (W/cm <sup>2</sup> ) at 500 ohms	0.000047	0.00033 (*0.000029)	Different	Difference arises from the subject device using passive rather than active recovery - no clinical impact, given that primary active phases are comparable.

### Summary of Differences

The subject Enso for Migraine and the predicate Cefaly Connected – OTC share the same intended use and fundamental TENS mechanism. There are several minor technological differences between the two devices. The Enso for Migraine features a smaller, lighter neurostimulator; a slightly higher voltage battery; and relies primarily on a mobile app for treatment control, whereas the predicate uses both an on-device button and app. The subject device’s gel pad is larger and differently shaped, resulting in a lower maximum current density, and it employs an asymmetrical biphasic waveform for charge recovery instead of the predicate’s symmetrical approach. The larger gel pad area contributes to lower maximum current density while maintaining comparable current amplitude, which does not reduce treatment effectiveness as current is not required to be tightly distributed in one spot for stimulation of superficial trigeminal nerve branches. Finite element modeling studies comparing the predicate's gel pad geometry with larger and more extended geometries found that the larger pad produced "negligible impact on the induced current flow pattern" in target nerves, spreading the same magnitude of induced field into the same nerve branches while providing safety benefits through reduced current density (Thomas et al., "Determination of Current Flow Induced by Transcutaneous Electrical Nerve Stimulation for the Treatment of Migraine: Potential for Optimization." Front. Pain Res. Lausanne Switz. 2021). Output parameters such as current, voltage, and frequency are similar, with only small differences that are not clinically significant. The Enso for Migraine app omits some optional tracking and reminder features found in the predicate’s app, and its packaging includes additional items such as cosmetic skin wipes and a quick start guide. None of these differences raise new questions of safety or effectiveness, and bench testing confirms that the Enso for Migraine performs equivalently to the predicate device.

## **Performance Testing - Bench**

Performance testing was completed to confirm that the device meets established specifications and requirements.

Non-clinical testing was performed to evaluate key aspects of device performance:

- Therapeutic Performance
  - including waveform characteristics, current density, and distribution
- Gel Pad and Skin Interface Performance
  - including adhesion, impedance, and reuse characteristics

Results of non-clinical bench testing are sufficient to demonstrate safety and effectiveness of the subject device and support a determination of substantial equivalence to the predicate, so animal and clinical performance testing were not necessary.

A human factors study was also completed to support a determination of substantial equivalence to the predicate and to establish safety and effectiveness of the subject device for an over-the-counter indication.

Results of performance testing (bench and human factors) demonstrated that the subject device is as safe and effective as the predicate with respect to the intended use.

## **Performance Testing - Clinical**

Clinical performance testing was not conducted for the subject device. Instead, clinical effectiveness and safety were established via analysis of published clinical literature for the legally marketed predicate device.

## **Conclusion**

The subject and predicate devices share a common intended use, and the differences in technological characteristics do not raise issues of safety and effectiveness. Results of performance testing demonstrate that the subject device is as safe and effective as the predicate with respect to the intended use. Therefore, the subject device can be concluded to be substantially equivalent to the predicate.