December 2, 2025

Aura Wellness, LLC
Scott Blomberg
Director of Regulatory
2208 Plantside Drive
Louisville, Kentucky 40299

Re: K250896
Trade/Device Name: Aura Wave
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: SGT
Dated: October 24, 2025
Received: October 24, 2025

Dear Scott Blomberg:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250896

Please provide the device trade name(s).

Aura Wave

Please provide your Indications for Use below.

The Aura Wave is indicated:
- To temporarily increase local blood circulation in healthy leg muscles
- To stimulate healthy muscles in order to improve or facilitate muscle performance

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

(as required by 21CFR 807.92)

I Submitter

Aura Wellness, LLC
2208 Plantside Drive
Louisville, KY 40299
Phone: 502-714-1993
Fax: 502-369-5226

Submitter Contact: Scott Blomberg
Submission Correspondent: scott@aurawell.com
Establishment Registration: 10081462
Submission Date: March 20, 2025

II Device

Proprietary or Trade Name: Aura Wave
Common/Usual Name: Powered Muscle Stimulator
Classification Name: Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation: 890.5850
Regulatory Class: 2
Product Code: SGT
Device Panel: Neurological and Physical Medicine Devices

III Predicate Device

Bemer Classic Set and Bemer Pro-Set (K210174)

IV Device Description

The Aura Wave system is a noninvasive physical medicine device that uses electrically generated magnetic fields to stimulate muscles in order to improve and facilitate muscle performance.

The Aura Wave is noninvasive, fully reusable (no disposable components such as electrodes) and have configurations allowing both home care and clinical professional use.

In addition to the main control unit, the Aura Wave has five accessory attachments (coils). The attachments vary in size and form which allows the operator to choose which attachment administers optimal treatment to the desired anatomical part of the body.

The device contains firmware that controls the user interface. Through this user interface, the operator controls the magnetic pulse generator intensity and duration of the treatment.

Accessories to the device

Name	Description	
Large Loop	For treatment of upper back and shoulders, and lower back	Provided with system
Butterfly Loop	For treatment of knee, ankle, foot, hand, arm and shoulder	Provided with system
Wings	For treatment of back, shoulders, and neck	Optional accessory
Half Body Mat	For treatment of back, lower back, hips, and hamstring muscles	Optional accessory
Paddle	For treatment of hip, thigh, buttocks, hands, and feet	Optional accessory

V Indication for Use

The Aura Wave is indicated:

• To temporarily increase local blood circulation in healthy leg muscles.

• To stimulate healthy muscles in order to improve or facilitate muscle performance.

Environments of use: Over the Counter (OTC), both home care and clinical professional use

VI Comparison of Technological Characteristics and Performance with the Predicate and Reference Devices

Table 1 below provides the summarized substantial equivalence comparison of general intended uses/actions, specific indications for use, equivalence of key clinical and technical features between subject and predicate device, along with a full listing of technical and conformance specifications.

Table 1: Comparison of Subject vs. Predicate and Reference Devices

		Aura Wave **Subject Device K250896**	BEMER Pro Set **Predicate Device K210174**	Nova HD+ **Reference Device K220938**
Classification Code	Identical	Primary: Powered Muscle Stimulator SGT 890.5850	Primary: Powered Muscle Stimulator NGX 890.5850	Primary: Powered Muscle Stimulator NGX 890.5850
Indication for Use	Similar	The Aura Wave is indicated: • To temporarily increase local blood circulation in healthy leg muscles. • To stimulate healthy muscles in order to improve and facilitate muscle performance	The BEMER therapy is indicated: • To temporarily increase local blood circulation in healthy leg muscles. • To stimulate healthy muscles in order to improve and facilitate muscle performance	The Nova HD+ is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance.
Primary Mode of Action	Identical	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via magnetic field induction	Non-invasive tissue stimulation via magnetic field induction
Therapy Timer	Similar The extended duration of the subject device does not represent a significant change in clinical application or safety. The increased timer flexibility does not alter the intended use or raise new questions of safety or effectiveness, and the two systems remain substantially equivalent in their therapeutic range.	1-90 minutes (10 minute default) Recommended treatment time is 10-20 minutes for a single location on the body.	8-20 minutes	1-20 minutes (10 minute default)

		Aura Wave **Subject Device K250896**	BEMER Pro Set **Predicate Device K210174**	Nova HD+ **Reference Device K220938**
Model (System)	Similar	Aura Wave	Pro Set	Nova HD+
Weight	Similar	8.1 pounds (3.7 kg)	System: 2.9 pounds (1.3 kg) [B.BOX Classic] System: 3.1 pounds (1.4 kg) [B.BOX Professional]	5.6 pounds (2.5 kg)
Dimensions (Main Unit):	Similar	11.9” x 13.7” x 4.6”	Public information not available	9.7” x 10.64” x 3.57”
Size of Therapy Area	Similar	50 in^2 (Paddle) to 573 in^2 (Wings)	Public information not available	147.2 in^2 (Large Loop)
Magnetic Field Output RMS Average	Similar	Up to 0.19 T	150 µT (max level)	Up to 1.8 mT
Maximum Induced Current*	The maximum induced current for the subject device does not raise safety or effectiveness concerns as it falls below the accepted standards for safe operation. In addition, the maximum induced current is similar to the reference device.	0.084 mA/cm^2	Public information not available	0.039 mA/cm^2
Pulse Repetition Rate	Similar	0.4 to 5.8 Hz	30 Hz	0.4 to 5.4 Hz
Pulse Duration	Similar	0.13 to 0.24 mS	.500 to .765 mS	0.6 to 0.7 mS
Power Consumption	Different but does not raise safety or effectiveness concerns	90 Watts maximum	30 Watts maximum	81.6 Watts maximum
Input Power	Similar	120 Vac, 50 or 60 Hz, 0.75 A	120/240 Vac, 50-60 Hz, 0.6 A; Battery Backup	120 Vac, 60 Hz, 0.68 A
Number of Output Channels	Similar	1	2	1
User Interface	Aura Wave and Nova HD+ identical	Simple 5-button interface	Touchscreen	Simple 5-button interface
Microprocessor controlled	Identical	Yes	Yes	Yes
Therapy Amplitude Control	Similar	Power level 1-20 controlled by operator	Power level 1-10 controlled by operator	Power level 1-10 controlled by operator
User-controlled therapy start/stop	Identical	Yes	Yes	Yes
Compliance with voluntary standards	Identical	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62366-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62366-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 62366-1 IEC 60601-1-11
Firmware developed per IEC 62304	Identical	Yes	Yes	Yes

*Induced current measured according to IEC 60601-2-10.

VII Equivalence Rationale

The subject device Aura Wave and the predicate device Bemer Pro Set are both noninvasive physical medicine devices that use electrically generated magnetic fields to stimulate muscles and other tissues for a variety of benefits to the patient. Those benefits include a temporary increase in blood circulation in healthy leg muscles, and the stimulation of healthy muscles in order to improve or facilitate muscle performance.

Both systems share the following characteristics:

- A main unit which is a solid-state microprocessor controlled electronic device and is powered from mains.
- One or more accessories which are attached to the main unit for the purpose of delivering magnetic field therapy to the patient.
- Relatively small (< 10 pounds) and can be easily transported.
- Tested to applicable safety and EMC standards for both home care and professional use environments.
- Operator adjustable therapy timer and adjustable power output.

The subject device Aura Wave, and the reference device Aura Nova HD+ share some key characteristics:

- Identical user interface.
- Very similar waveform output in terms of waveform shape and pulse rate.
- Similar induced current (estimated for tissue).
- Both use the Aura Large Loop accessory.
- Both offer one operating channel.

The subject device Aura Wave, and the predicate device Bemer Pro Set both offer a variety of accessories to give the user the option of treating either a targeted part of the anatomy with the smaller accessories to large areas of the anatomy such as the back with the largest accessories.

Non-clinical Testing

Performance testing demonstrated that the subject treatment applicator performed equivalent to the predicate applicator. Testing included:

Performance testing involved multiple measurements of:

- Signal waveform output (volts) generated from Aura Wave with its applicators.
- Magnetic flux output (mT) generated from the applicator at all signal intensity input levels 1-20.

Software

- All software features documented and tested in accordance with IEC 62304 for ‘Moderate’ level of concern.

Electrical / EMC evaluated per

- IEC 60601-1 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance
- IEC 60601-1-2 - Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-11 - 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
- IEC 60601-1-6 - Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 62366-1 - Medical devices — Part 1: Application of usability engineering to medical devices

Biocompatibility

- ISO 10993-1 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 - Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 - Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization

Clinical Testing

Not applicable. No clinical testing was performed.

CONCLUSIONS

The analysis of the differences between Aura Wave and the predicate device does not raise new questions of safety and effectiveness for the subject device. Based on device performance test results, Aura Wellness determines that the Aura Wave system performs within its design specifications and is equivalent to the predicate device.

The information in this 510(k) submission demonstrates that the Aura Wave system is substantially equivalent to the predicate device.