August 22, 2023

Aura Wellness, LLC
Scott Blomberg
Director of Regulatory Affairs
11530 Electron Drive
Louisville, Kentucky 40299

Re: K220938
Trade/Device Name: Nova HD+
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: August 21, 2023
Received: August 21, 2023

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 (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,

Heather L. Dean -S

Heather Dean, Ph.D
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

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)*
K220938

Device Name
Nova HD+

Indications for Use *(Describe)*
The Nova HD+ is intended for use by adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance.

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

K220938

(as required by 21CFR 807.92)

I Submitter

Aura Wellness, LLC
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Phone: 502-714-1993
Fax: 502-369-5226

Submitter Contact: Scott Blomberg
Submission Correspondent: scott@aurawell.com
Establishment Registration: 10081462
Submission Date: August 21, 2023

II Device

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

III Predicate Device

Bemer Classic Set and Bemer Pro-Set (K210174)

IV Device Description

The Nova HD+ 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 Nova HD+ 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 Nova HD+ includes a large loop coil applicator (coils) which allow the operator to administer 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.

V Indication for Use

The Nova HD+ is intended for use by adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance.

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

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VI Comparison of Technological Characteristics and Performance with the Predicate

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

		Nova HD+ **Subject Device** **K220938**	BEMER Pro Set **Predicate Device** **K210174**
Classification Code	Identical	Primary: Powered Muscle Stimulator NGX 890.5850	Same
Indication for Use	Similar	The Nova HD+ is intended for the stimulation of healthy muscles in order to improve or 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
Primary Mode of Action	Identical	Non-invasive tissue stimulation via magnetic field induction	Same
Therapy Timer	Similar	1-20 minutes	8-20 minutes
Model (System)	Similar	Nova HD+	Pro Set
Weight	Similar	System: 5.6 pounds (2.5 kg)	System: 2.9 pounds (1.3 kg) [B.BOX Classic] System: 3.1 pounds (1.4 kg) [B.BOX Professional]
Dimensions (Main Unit):	Similar	9.7” x 10.64” x 3.57”	Public information not available
Size of Therapy Area	Similar	147.2 in^2 (Large Loop)	Public information not available
Magnetic Field Peak Frequency	Different but does not raise any safety concerns	1.58 kHz	Public information not available.
Average Flux Density (Applicator)	Different but does not raise any safety concerns	1.8 mT (max level)	150 µT (max level)
Power Consumption	Different but does not raise safety or effectiveness concerns	81.6 Watts maximum	30 Watts maximum
Input Power	Similar	100-130 Vac, 60 Hz, 0.68 A	100-240 Vac, 50-60 Hz, 0.6 A; Battery Backup

		Nova HD+ **Subject Device** **K220938**	BEMER Pro Set **Predicate Device** **K210174**
Number of Output Channels	Similar	1	2
Microprocessor controlled	Identical	Yes	Same
Therapy Amplitude Control	Identical	Power level 1-10 controlled by operator	Power level 1-10 controlled by operator
User-controlled therapy start/stop	Identical	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	Same
Firmware developed per IEC 62304	Identical	Yes	Same

VII Equivalence Rationale

Principle of Operation

The principle of operation for the Nova HD+ is identical to the predicate, Bemer Classic Set and Bemer Pro-Set (K210174). The Nova HD+ and the predicate systems deliver therapeutic massage to the patient through the use of low-level magnetic fields administered directly to the body.

Use Mode

The use of the Nova HD+ is essentially the same as the predicate device. Both units have main control unit. Both units have interchangeable treatment applicators (coils) for administering the therapy to desired area of the body. The controls on the control unit allow the user to select the time and intensity of the therapy and allow for adjustment of the intensity during the session.

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 Nova HD+ with its applicators.
- Magnetic flux output (mT) generated from the applicator at all signal intensity input levels 1-10.

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.

CONCLUSIONS

The analysis of the differences between Nova HD+ 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 Nova HD+ system performs within its design specifications and is equivalent to the predicate device.

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