July 2, 2025

Sofwave Medical Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street
Suite 2300
Philadelphia, Pennsylvania 19103

Re: K251746
Trade/Device Name: Pure Impact
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 6, 2025
Received: June 6, 2025

Dear Janice Hogan:

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,

Julia E. Slocomb -S 2025.07.02 08:13:04 -04'00'

For Tushar Bansal, PhD
Acting 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

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.	K251746

Please provide the device trade name(s).

Pure Impact

Please provide your Indications for Use below.

• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
• Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.
• The Pure Impact is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Pure Impact is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The various types of muscle work that the Pure Impact can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Pure Impact may therefore be considered a technique of muscle training.

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

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

510(k) SUMMARY

Sofwave Medical's Pure Impact Device

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Sofwave Medical Ltd.
1 Ha-Otsma St.
Yokneam Ilit,
Israel 2069200

Submission Correspondent:

Ruthie Amir, MD, Chief Medical Officer
ruthie@sofwave.com
+972543003164

Date Prepared: July 1, 2025

Name of Device (Trade Name):

Pure Impact

Common Name:

Electrical Muscle Stimulator

Classification Name:

21 CFR 890.5850 (Powered Muscle Stimulator for Muscle Conditioning)
Class II
Product Code NGX

Predicate Devices

Sofwave Medical's SofWave System (K250146)

Intended Use / Indications for Use

Pure Impact is indicated to be used for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.
- Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.
- The Pure Impact is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Pure Impact is not intended to be used in conjunction with therapy or treatment of medical diseases or medical

conditions of any kind. The various types of muscle work that the Pure Impact can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Pure Impact may therefore be considered a technique of muscle training.

The indications for use statement for the subject device is identical to that of the previously cleared Pure Impact Module of the SofWave System in K250146.

Device Description/Technological Characteristics

Pure Impact device provides both training and physical therapy using Electrical Muscle Stimulation (EMS). The EMS is provided through electrodes that are controlled by the Touch Control Module.

The system includes:

- Touch Control Module
- Pure Impact™ Wireless Stimulation Modules
- Pure Impact™ Electrode Pads
- Pure Impact™ Charging Station

The Touch Control Module runs the Pure Impact™ program and displays the user interface, which provides the full range of controls to identify the patient and the required treatment. The Pure Impact™ Wireless Stimulation Modules provide EMS to selected body locations on the patient and communicate to the Touch Control Module through Bluetooth Low Energy (BLE). Each Stimulation Module contains a main stimulation unit and several stimulation subunits, each of which is attached to a Pure Impact™ Electrode Pad placed on the patient. The Pure Impact™ Electrode Pads are disposable and intended for single patient, single use only. They contain a hydrogel adhesive to attach to the selected body locations on the patient and magnetic connectors to attach to the Stimulation Modules. The Pure Impact™ Charging Station charges the Stimulation Modules.

The Pure Impact Device is intended for use by health professionals under the supervision of a physician: nurses, aestheticians, physician assistants and any other health professionals working in the environment of aesthetic clinics (dermatologists, plastics, medical spa).

Comparison of Technological Characteristics with the Predicate Device

The subject Pure Impact device is a modification to the company's Pure Impact Module of the SofWave System cleared in K250146. The only changes are related to the standalone PC, as well as the GUI and software updates. While the Pure Impact Module of the SofWave device is controlled from the SofWave main console, the control unit of the Pure Impact standalone device is an all-in-one PC with an independent SW and GUI. No changes were made to the Pure Impact Charging Station Unit, Pure Impact Wireless Stimulation Modules, or Pure Impact Electrode Pads. Furthermore, the change does not affect the treatment protocols, stimulation parameters, or energy delivery.

To accommodate the proposed Pure Impact device as a standalone device, software changes were made, including the changes in the GUI. The changes do not affect the application of Pure Impact on the human body, the electrical requirements, or the energy specifications. The changes do not affect energy delivery, mechanism of function, treatment parameters limits, or the total

energy delivered by the device, nor do they present any new questions of safety or effectiveness, as the actual output is determined by the treatment physician.

Verification Testing

In accordance with Sofwave's design control procedures, risk analysis was conducted to assess the impact of the modifications on the device. Verification testing demonstrates that the modified device functions as specified and is as safe and effective as the cleared predicate device.

In all instances, the subject pure Impact device performed as intended.

- Software verification and validation and cybersecurity testing was performed, and demonstrated that the software performs as intended;

- Electrical Safety and Electromagnetic Compatibility was established in accordance with IEC 60601-1-2, IEC 60601-1, IEC 60601-1-6, and IEC 60601-2-10.

Conclusion

The subject device and its predicate have the same intended use/indications, similar technological characteristics, and the same principles of operation. Moreover, the minor differences in technological characteristics do not present different questions of safety or effectiveness as compared to the predicate device. Verification testing according to the company's design control procedures demonstrates that the subject device is as safe and effective as the predicate device. Thus, the Pure Impact device is substantially equivalent to the predicate device.

Substantial Equivalence Chart – Pure Impact Device

	Subject Device	**Predicate Device (K250146)**	
Product	**Pure Impact Device**	**Pure Impact Module of the SofWave system**	**Conclusion**
Classification Name	Powered muscle stimulator	Powered muscle stimulator	Same
Product Code	NGX	NGX	Same
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	Same
Panel	Physical Medicine	Physical Medicine	Same
Class	Class II	Class II	Same
Indication for use	Indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas. • The Pure Impact is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Pure Impact is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The various types of muscle work that the Pure Impact can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Pure Impact may therefore be considered a technique of muscle training.	Indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas. • The Pure Impact is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Pure Impact is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The various types of muscle work that the Pure Impact can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Pure Impact may therefore be considered a technique of muscle training.	Same
Power source	Console Power source: 100-240AC, 50/60Hz Rechargeable Lithium Ion Polymer Battery Pack 3.7 V Nominal Voltage: 3.7V Nominal Capacity: 600mA	Console Power source: 100-240AC, 50/60Hz Rechargeable Lithium Ion Polymer Battery Pack 3.7 V Nominal Voltage: 3.7V Nominal Capacity: 600mA	Same
Patient Leakage Current - Normal Condition	Normal condition = less than 100µA	Normal condition = less than 100µA	Same
Display	Touch screen LCD	Touch screen LCD	Same
Number of Output Channels	Maximum of 6 channels per treatment (up to 2 on each body area)	Maximum of 6 channels per treatment (up to 2 on each body area)	Same

	Subject Device	**Predicate Device (K250146)**	
Product	**Pure Impact Device**	**Pure Impact Module of the SofWave system**	**Conclusion**
Method of Channel Isolation	Separate units for pulse generation (wireless units). Line power is NA	Separate units for pulse generation (wireless units). Line power is NA	Same
Regulated Current or Regulated Voltage	Regulated current	Regulated current	Same
Software/Firmware/ Microprocessors Controls?	Yes	Yes	Same
Automatic Overload Trip?	Yes	Yes	Same
Automatic No-Load Trip	Yes	Yes	Same
Automatic Shut off?	Yes	Yes	Same
Patient Override Control?	Yes	Yes	Same
Indicator Display: On/Off Status?	Yes	Yes	Same
Low Battery?	Yes	Yes	Same
Voltage/Current Level?	Yes (Energy level)	Yes (Energy level)	Same
Timer Range (minutes)	Up to 60 minutes	Up to 60 minutes	Same
Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, and ISO14971	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, and ISO14971	Same
Compliance With 21 CFR 898	Yes, the electrode cable can never be plugged in the AC socket, not even accidentally	Yes, the electrode cable can never be plugged in the AC socket, not even accidentally	Same

Comparison of Waveform Specifications

	Subject Device				Pure Impact Module of the SofWave System (K250146)			
	Basic	**Focused**	**Enhanced**	**PlyoPulse**	**Basic**	**Focused**	**Enhanced**	**PlyoPulse**
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic	Symmetrical Biphasic
Shape	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave
Maximum Output Voltage	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)
	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)
	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)
Maximum Output Current	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)	102 mA pp @ 500 Ω (± 10%)
	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)
	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)
Pulse Width	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω	50 to 500 µS (± 10%) @500Ω
Frequency	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω
For Multiphasic Waveform Symmetrical Phases?	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic
Number of Output Channels	6	6	6	6	6	6	6	6
Net Charge	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic	0 uC @500Ω (Being Biphasic

	Subject Device				Pure Impact Module of the SofWave System (K250146)			
	Basic	**Focused**	**Enhanced**	**PlyoPulse**	**Basic**	**Focused**	**Enhanced**	**PlyoPulse**
	in nature the net charge would be Zero)	in nature the net charge would be Zero)	in nature the net charge would be Zero)	in nature the net charge would be Zero)	in nature the net charge would be Zero)	in nature the net charge would be Zero)	in nature the net charge would be Zero)	in nature the net charge would be Zero)
Maximum Phase Charge	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω
Maximum Current Density	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω	2.0 mA/cm^2 @ 500Ω
	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes
Maximum Power Density	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load
	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes	*measured with 50 x 50mm rectangular electrodes
Burst Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ON Time	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds
OFF Time	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds