December 14, 2023

Sofwave Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K232455
Trade/Device Name: SofWave System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, OHV
Dated: November 17, 2023
Received: November 17, 2023

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.

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232455

Device Name
SofWave System

Indications for Use *(Describe)*
The SofWave System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial lines and wrinkles, lift the eyebrow, and lift lax submental (beneath the chin) and neck tissue; which can also affect the appearance of lax tissue in the submental and neck region for subjects aged 22 and older. The SofWave System is also indicated for short-term improvement in the appearance of cellulite.

The Pure Impact module is indicated to be used for:

• Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.

• Strengthening, toning and firming of buttocks and thighs.

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

Sofwave Medical's SofWave System

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

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

Submission Correspondent:

Janice M. Hogan
Hogan Lovells US LLP
janice.hogan@hoganlovells.com
(267) 675-4611

Date Prepared: December 12, 2023

Name of Device:

SofWave System

Classification Name:

21 CFR 878.4590 (Focused Ultrasound Stimulator System for Aesthetic Use), Class II, product code OHV

21 CFR 890.5850 (Powered Muscle Stimulator), Class II, product code NGX

Predicate Devices

Sofwave Medical's SofWave System (K230820) (Predicate Device)

Johari Digital Healthcare Limited's truSculpt flex (K212866) (Predicate Device)

DJO LLC's Compex Wireless USA (K143551) (Reference Device)

Intended Use / Indications for Use

The SofWave System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial lines and wrinkles, lift the eyebrow, and lift lax submental (beneath the chin) and neck tissue; which can also affect the appearance of lax tissue in the submental and neck region for subjects aged 22 and older. The SofWave System is also indicated for short-term improvement in the appearance of cellulite.

The Pure Impact module is indicated to be used for:

- Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.

- Strengthening, toning and firming of buttocks and thighs.

Technological Characteristics

The SofWave System is an ultrasound system intended for aesthetic purposes. The system generates high frequency ultrasonic pulses that elevate the temperature in the dermis layer and cause controlled isolated areas of thermal damage. The SofWave System consists of two main functional components: 1) the console and 2) the applicator. The console includes the power sources, cooling unit, electrical components, IoT, and the user interface. The applicator is comprised of an array of ultrasonic transducers that emit continuous acoustic waves and an active cooling element that is used to cool the skin area in contact with the applicator. The applicator is connected by a flexible cable to the console.

The subject device of this 510(k) adds an EMS module ("Pure Impact") to the previously cleared SofWave ultrasound system (K230820). The EMS module is wirelessly connected to and controlled by the SofWave console. It functions independently from the existing ultrasound system. The user selects either the ultrasound treatment or the EMS treatment, but not both, at the beginning of the treatment.

Comparison of Technological Characteristics with the Predicate Device

The SofWave System has similar technological characteristics compared to the predicate devices. The subject SofWave device is almost identical to the previously SofWave device that was cleared in K230820, except minor hardware changes, which do not significantly affect clinical functionality or performance specifications of the device, and have been verified and tested. The treatment parameters and energy specifications of the device remain identical to that cleared in K230820 for the ultrasound module. The purpose of this 510(k) notification is to add a wirelessly connected EMS module (Pure Impact) to the existing system. Importantly, the inclusion of the Pure Impact module does not affect the performance of the SofWave module; nor does it require any significant hardware modifications to the SofWave console or the applicator.

The Pure Impact module has similar technological characteristics as the truSculpt flex predicate (K212866). Both devices are electrical muscle stimulators that generate electrical impulses, which are delivered through electrodes on the skin in direct proximity to the muscles to be stimulated. Both devices contract muscles rhythmically to achieve the intended use of strengthening, firming, and toning the muscles of the abdomen, thighs, and buttocks.

Both Pure Impact and truSculpt flex consist of a console with a touchscreen control panel and stimulation electrodes. For both devices, all system functions are controlled through the console. While there are minor differences in the connection between console and electrodes, these differences do not raise new questions of safety or effectiveness. For both devices, the same types of safety questions arise, i.e., whether the devices can safely stimulate the muscle and not result in injury to the patient. Also, the same types of efficacy questions arise, i.e., whether the devices can effectively achieve the intended use of strengthening, firming, and toning the muscle.

Furthermore, wireless stimulation of muscles has been cleared by FDA for other devices with similar intended use, such as the Compex Wireless reference device (K143551).

	Subject device	**Predicate Device K230820**
Product	SofWave (SofWave Module)	SofWave
Regulation	21 CFR 878.4590	21 CFR 878.4590
Product code	OHV	OHV
Indications	The SofWave System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial lines and wrinkles, lift the eyebrow, and lift lax submental (beneath the chin) and neck tissue; which can also affect the appearance of lax tissue in the submental and neck regions for subjects aged 22 and older. The SofWave System is also intended for short-term improvement in the appearance of cellulite.	The SofWave System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial lines and wrinkles, lift the eyebrow, and lift lax submental (beneath the chin) and neck tissue; which can also affect the appearance of lax tissue in the submental and neck regions for subjects aged 22 and older. The SofWave System is also intended for short-term improvement in the appearance of cellulite.
Technology	High Intensity non-focused Ultrasound	High Intensity non-focused Ultrasound
System components	• Console that includes the power sources, electrical components and user interface (touchscreen) • Handpiece	• Console that includes the power sources, electrical components and user interface (touchscreen) • Handpiece
Energy delivered / fluence	3-5 Joule per PZT (or 6-10 J/cm^2)	3-5 Joule per PZT (or 6-10 J/cm^2)
Epidermal impact	Non-invasive	Non-invasive
Treatment area	15 or 35 mm^2	15 or 35 mm^2
User interface	LCD Touch Screen Graphic User Interface	LCD Touch Screen Graphic User Interface
	Subject Device	**Predicate Device K212866**
Product	SofWave (Pure Impact Module)	truSculpt flex
Classification Name	Powered muscle stimulator	Powered muscle stimulator
Product Code	NGX	NGX
Regulation Number	21 CFR 890.5850	21 CFR 890.5850
Panel	Physical Medicine	Physical Medicine
Class	Class II	Class II
Indication for use	indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of buttocks and thighs.	indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen. • Strengthening, toning and firming of buttocks and thighs.
Target population	It is to be used by adults only.	It is to be used by adults only.

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	100-240AC, 50/60Hz, 75VA
Patient Leakage Current - Normal Condition	Normal condition = less than 100µA	Normal condition = less than 100µA
Components	Console, 8 stimulation modules (up to 4 units working in parallel), Maximum of 16 electrode pads per treatment	Main unit, 8 Stainless steel reusable electrodes pairs (16 electrodes) 4 electrode lead wires 1 AC Power Cord 4 Hydrogel pads 2 reusable silicone belts (cummerbunds)
Display	15” LCD	12” LCD
Number of Output Channels	Maximum of 4 channels per treatment	Maximum of 4 channels per treatment
Method of Channel Isolation	Separate units for pulse generation (wireless units). Line power is NA	Transformer
Regulated Current or Regulated Voltage	Regulated current (all channels)	Tran conductance
Software/Firmware/ Microprocessors Controls?	Yes	Yes
Automatic Overload Trip?	Yes	Yes
Automatic No-Load Trip	Yes	No
Automatic Shut off?	Yes	Yes
Patient Override Control?	Yes	Yes
Indicator Display: On/Off Status?	Yes	Yes
Low Battery?	Yes	N/A
Voltage/Current Level?	Yes (Energy level)	Yes
Timer Range (minutes)	Up to 60 minutes	45 Minutes - For Classic mode 15 Minutes - for Flex+ mode
Compliance with Voluntary Standards?	Yes IEC 60601-1, IEC 60601-1-2,IEC60601-2-10, and ISO14971	Yes IEC 60601-1, IEC 60601-1-2,IEC60601-2-10, and ISO14971
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
Housing Material and construction	PCABS510 for console covers & end point shells	ABS Plastic Body
Operating Temperature	Temperature: 5°C to +30°C Relative Humidity: 30% to 70 %	Temperature: +15°C to +35°C Relative Humidity: 30 % to 75 % (noncondensing) Barometric pressure: 700 hPa to 1060 hPa
Transport and storage environment	Temperature: +5°C to +30°C Relative Humidity: 30% to 70% (noncondensing)	Temperature: +5°C to +45°C Relative Humidity: 10% to 85% (noncondensing)

Notably, the subject Pure Impact Module has similar output waveform specifications as both the truSculpt flex predicate device and the Compex Wireless reference device. Differences in the maximum output voltage and maximum output current are minor and not clinically relevant. For all other parameters, the subject device's range is within that for the predicate and reference devices, thus not impacting substantial equivalence.

Comparison of Waveform Specifications

	SofWave Pure Impact Module			truSculpt flex Predicate Device (K212866)			Compex Wireless Reference Device (K143551)
	Basic	**Focused**	**Enhanced**	**Tone**	**Prep**	**Sculpt**	
Waveform	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	Modulated Sine Wave	Rectangular
Maximum Output Voltage	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	51 Vpp @ 500 Ω (± 10%)	70 Vpp @ 500 Ω (± 10%)	100 Vpp @ 500 Ω (± 10%)	100 Vpp @ 500 Ω (± 10%)	60 Vpp @ 500 Ω (± 10%)
	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	204 Vpp @ 2 kΩ (± 10%)	125 Vpp @ 2 kΩ (± 10%)	125 Vpp @ 2 kΩ (± 10%)	125 Vpp @ 2 kΩ (± 10%)	180 Vpp @ 2 kΩ (± 10%)
	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	228 Vpp @ 10 kΩ (± 10%)	150 Vpp @ 10KW (± 10%)	133 Vpp @ 10 kΩ (± 10%)	135 Vpp @ 10 kΩ (± 10%)	180 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%)	140 mA pp @ 500 Ω	200 mA pp @ 500 Ω	200 mA pp @ 500 Ω	120 mA pp @ 500 Ω
	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	102 mA pp @ 2 kΩ (± 10%)	62.5 mA pp @ 2 kΩ	62.5 mA pp @ 2 kΩ	62.5 mA pp @ 2 kΩ	90 mA pp @ 2 kΩ
	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	22 mA pp@ 10 kΩ (± 10%)	15 mA pp @ 10 kΩ	13 mA pp @ 10 kΩ	13.5 mA pp @ 10 kΩ	18 mA pp @ 10 kΩ
Pulse Width	250 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	350 µS (± 10%) @500Ω	125 µS (± 10%) @500Ω	125 µS (± 10%) @500Ω	300 to 400 µs

	SofWave Pure Impact Module			truSculpt flex Predicate Device (K212866)			Compex Wireless Reference Device (K143551)
	Basic	**Focused**	**Enhanced**	**Tone**	**Prep**	**Sculpt**	
Frequency	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	99 Hz (± 10%) @ 500 Ω	Channel1: 4000 Hz (± 10%) @500 Ω Channel 2: 4001 – 4100 Hz (± 10%) @500 Ω Resultant: 1 – 100 Hz	4000 Hz (± 10%) @ 500 Ω Resultant: 1 – 100 Hz	1 to 120 Hz
For multiphasic Waveform Symmetrical Phases?	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic	Yes	Yes, Symmetrical Biphasic	Symmetrical
Phase duration	250 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	350 µS (± 10%)	125 µS (± 10%)	125 µS (± 10%)	300 - 400 µs
Net charge	0 uC @500Ω (Being Biphasic in nature the net charge would be Zero)	0 uC @500Ω (Being Biphasic in nature the net charge would be Zero)	0 uC @500Ω (Being Biphasic in nature the net charge would be Zero)	0 µC @500 Ω (Being Biphasic in nature the net charge would be Zero)	0 µC @500 Ω (Being Biphasic in nature the net charge would be Zero)	0 µC @500 Ω (Being Biphasic in nature the net charge would be Zero)	0 µC @ 500Ω Excitation pulse fully compensated
Maximum Phase Charge	17.85 µC @ 500Ω	17.85 µC @ 500Ω	17.85 µC @ 500Ω	24.5 µC @ 500 Ω Load	12.5 µC @ 500 Ω Load	12.5 µC @ 500 Ω Load	48 µC @ 500Ω

	SofWave Pure Impact Module			truSculpt flex Predicate Device (K212866)			Compex Wireless Reference Device (K143551)
	Basic	**Focused**	**Enhanced**	**Tone**	**Prep**	**Sculpt**	
Maximum Current density	2.04 mA/cm^2 @ 500Ω	2.04 mA/cm^2 @ 500Ω	2.04 mA/cm^2 @ 500Ω	2.02 mA/cm^2	2.88 mA/cm^2	2.88 mA/cm^2	1.49 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 59 x 59mm rectangular electrodes	*measured with 59 x 59mm rectangular electrodes	*measured with 59 x 59mm rectangular electrodes	*size of electrodes not publicly available
Maximum Power Density	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.052 Watt/cm² @ 500Ω Load	0.070 Watt/cm^2	0.144 Watt/cm^2	0.144 Watt/cm^2	27.6 mW/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 59 x 59mm rectangular electrodes	*measured with 59 x 59mm rectangular electrodes	*measured with 59 x 59mm rectangular electrodes	*size of electrodes not publicly available
ON Time	6 seconds	6 seconds	6 seconds	6 seconds	NA	NA	NA
OFF Time	4 seconds	4 seconds	4 seconds	4 seconds	NA	NA	NA

Performance Data

The following nonclinical performance testing has been conducted to support the substantial equivalence of the SofWave System to its predicate device. In all instances, the SofWave System functioned as intended.

- Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993-1.
- Software verification and validation 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, IEC 60601-2-10, IEC 60601-2-62, and IEC 62133.
- Functional bench testing was conducted to verify that the device performance meets its specifications.
- Usability validation study was conducted to show that the users can safety use the device according to the instructions for use.

Conclusion

SofWave has the same general intended use and indications, similar technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the subject and the predicate devices do not raise different questions of safety or effectiveness. Performance testing of the device has demonstrated that the device performs as intended and thus is substantially equivalent to its predicates.