U.S. FOOD & DRUG ADMINISTRATION

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April 18, 2025

Sofwave Medical Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19312

Re: K250146
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: January 20, 2025
Received: January 21, 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,

Tushar Bansal -S

for Heather Dean, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250146

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 intended for short-term improvement in the appearance of cellulite and the treatment of Acne Scars. The SofWave System is indicated to improve the appearance of skin laxity on the upper arms.

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.
• 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.

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.

K250146

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

Contact Person:
Ruthie Amir, MD, Chief Medical Officer
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+972543003164

Date Prepared: March 20, 2025

Name of Device:

SofWave System

Classification Name:

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

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

Predicate Devices

Sofwave Medical's SofWave System (K241685, K233104) (Predicate Device)

XBody Hungary Kft.'s XBody Go USA, XBody Pro USA (K221200) (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 intended for short-term improvement in the appearance of cellulite and the treatment of Acne Scars. The SofWave System is indicated to improve the appearance of skin laxity on the upper arms.

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.
- 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.

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 three main functional components: 1) the console; 2) the applicator; and 3) EMS Module (Pure Impact). The console includes the power sources, cooling unit, electrical components, IoT, BLE, and the user interface. The applicator is comprised of an array of ultrasonic transducers that emit continuous acoustic waves at 10-12 MHz 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 EMS module is wirelessly connected to and controlled by the SofWave console. It functions independently from the ultrasound system. The user selects either the ultrasound treatment or the EMS treatment, but not both, at the beginning of the treatment.

Comparison with the Predicate Devices

The indications for use statement for the subject device is similar to the indications for use of the previously cleared SofWave device in K241685. Regarding the SofWave module, the indications for use statement now reflects both previously cleared indications in K241685 and the indications for acne scars and skin laxity on the upper arms, which were cleared in K233104. Regarding the Pure Impact module, the additional indication for muscle training is identical to the language used in the XBody predicate (K221200).

The SofWave module is almost identical to the previous SofWave device that was cleared in K241685, other than a few minor changes made to the hardware of the cleared device. These minor modifications do not change the treatment parameters or energy specification, nor do they present any new questions of safety or effectiveness.

The subject Pure Impact module is very similar to the predicate SofWave device that was cleared in K241685. No hardware changes were made to the cleared SofWave device's Pure Impact module. The software has been updated to allow the additional indication for muscle training. The Pure Impact module also has similar technology to the XBody predicate device (K221200). Both devices are electrical muscle stimulators that generate electrical pulses, which are delivered through electrodes on the skin in direct proximity to the muscles to be stimulated. Both devices contract muscles rhythmically to improve or facilitate muscle performance. Both the Pure Impact module of SofWave system and XBody consist of a console with a touchscreen control panel and

wireless, lithium battery-powered stimulation modules. For both devices, all system functions are controlled through the console. During a treatment session, electrical stimulation is delivered to the treatment area at the selected treatment mode and intensity.

The minor differences in the subject device's technological characteristics compared to the predicate devices do not raise different questions of safety or effectiveness.

Table 1: Substantial Equivalence Chart – SofWave Module

	Subject Device K250146	**Predicate Device K241685**
Product	SofWave (SofWave Module)	SofWave (SofWave Module)
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 *and the treatment of Acne Scars. The SofWave System is indicated to improve the appearance of skin laxity on the upper arms.*	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 *and the treatment of Acne Scars. The SofWave System is indicated to improve the appearance of skin laxity on the upper arms.* (*Cleared in K233104*)
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 per PZT	3-5 Joule per PZT (Lift and Precise applicators) 2.6-7 Joule per PZT (Smooth/LiftHD applicator)	3-5 Joule per PZT (Lift and Precise applicators) 2.6-7 Joule per PZT (Smooth/LiftHD applicator)
Epidermal Impact	Non-invasive	Non-invasive
Treatment Area	15, 35, or 70 mm^2	15, 35, or 70 mm^2
User Interface	LCD Touch Screen Graphic User Interface	LCD Touch Screen Graphic User Interface

Table 2: Substantial Equivalence Chart – Pure Impact Module

	Subject Device (K250146)	Predicate Device (K241685)	Predicate Device (K221200)	Reference Device (K143551)
Product	**SofWave (Pure Impact Module)**	**SofWave (Pure Impact Module)**	**XBODY Go USA and XBODY Pro USA**	**Compex Wireless USA**
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850
Classification Name	Powered muscle stimulator	Powered muscle stimulator	Powered muscle stimulator	Powered muscle stimulator
Product Code	NGX	NGX	NGX	NGX
Indications for Use	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. • 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 Pure Impact module 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 XBODY Go USA and XBODY Pro USA is a machine with electronic muscle stimulation based on EMS technology. The device is specifically designed as an addition to other sports and for training muscles. It must be used for only healthy muscles and clients, not for rehabilitation purposes. • The XBODY Go USA and XBODY Pro USA is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The XBODY Go USA and XBODY Pro USA is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the XBODY Go USA and XBODY Pro USA training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated. • The XBODY Go USA and XBODY Pro USA electrical impulses allow the triggering of action potentials on motoneurons of motor nerves (excitations). These excitations of motoneurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle	• The Compex Wireless USA is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only. The Compex Wireless USA is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is contraindicated. The work imposed on the muscles by the Compex Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different

	Subject Device (K250146)	Predicate Device (K241685)	Predicate Device (K221200)	Reference Device (K143551)
Product	**SofWave (Pure Impact Module)**	**SofWave (Pure Impact Module)**	**XBODY Go USA and XBODY Pro USA**	**Compex Wireless USA**
			fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. • The various types of muscle work that the XBODY Go USA and XBODY Pro USA can impose on the stimulated muscles are able to improve or facilitate muscle performance. The XBODY Go USA and XBODY Pro USA may therefore be considered a technique of muscle training.	types of muscle work can be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.
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	Li-ion Battery 4x 3.7V (3.4 Ah)	Remote: : Lithium Polymer (LiPo) rechargeable 3.7[V] / ⩾ 1500[mAh] Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ⩾ 450[mAh]
Patient Leakage Current - Normal Condition	Normal condition = less than 100µA	Normal condition = less than 100µA	N/A	N/A
Display	Touch screen LCD	Touch screen LCD	Touch screen LCD	LCD
Number of Output Channels	Maximum of 6 channels per treatment (up to 2 on each body area)	Maximum of 4 channels per treatment (up to 2 on each body area)	6 output channels, but 12 independently regulated outputs	4 channels
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	N/A	N/A
Regulated Current or Regulated Voltage	Regulated current	Regulated current	Regulated voltage	Regulated current

	Subject Device (K250146)	Predicate Device (K241685)	Predicate Device (K221200)	Reference Device (K143551)
Product	**SofWave (Pure Impact Module)**	**SofWave (Pure Impact Module)**	**XBODY Go USA and XBODY Pro USA**	**Compex Wireless USA**
Software/Firmware/ Microprocessors Controls?	Yes	Yes	Overload trip detects short-circuit, No-load trip detects circuit break, battery voltage monitoring, hardware error detection at startup, and watchdog monitoring.	Yes
Automatic Overload Trip?	Yes	Yes		Yes
Automatic No-Load Trip	Yes	Yes		Yes
Automatic Shut off?	Yes	Yes		Yes
Patient Override Control?	Yes	Yes		Yes
Indicator Display: On/Off Status?	Yes	Yes	N/A	Yes
Low Battery?	Yes	Yes	N/A	Yes
Voltage/Current Level?	Yes (Energy level)	Yes (Energy level)	N/A	Yes (Energy level)
Timer Range (minutes)	Up to 60 minutes	Up to 60 minutes	N/A	Up to 48 minutes
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	IEC 60529, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304, IEC 62366-1	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304, IEC 62366, 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	N/A	Yes.
Housing Material and Construction	PCABS510 for console covers & end point shells	PCABS510 for console covers & end point shells	Plastic	N/A

Notably, the subject Pure Impact module has very similar output waveform specifications as the XBody predicate device and the Compex reference device. All parameters are similar between the devices. Differences are minor and not clinically relevant.

Table 3: Comparison of Waveform Specifications

	Subject Device (K250146)				SofWave Pure Impact (K241685)				XBody (K221200)	Compex Wireless Reference Device (K143551)
	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	Symmetrical Biphasic	Symmetrical biphasic
Shape	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Rectangular	Rectangular
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%)	20.8V @ 500Ω	60 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%)		180 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%)		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%)	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%)	41.6 mA @ 500Ω	120 mA pp @ 500 Ω
	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%)		90 mA pp @ 2 kΩ
	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%)		18 mA pp @ 10 kΩ
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	250 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	50-500 µS	300 to 400 µS
Frequency	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-150Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-150 Hz	1 to 120 Hz
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	Yes, Symmetrical Biphasic	Yes, Symmetrical Biphasic
Number of Output Channels	6	6	6	6	4	4	4	4	6	4
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 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 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 @ 500Ω (each phase uses symmetric waveform)	0 µC @ 500Ω Excitation pulse fully compensated

	Subject Device (K250146)				SofWave Pure Impact (K241685)				XBody (K221200)	Compex Wireless Reference Device (K143551)
	Basic	**Focused**	**Enhanced**	**PlyoPulse**	**Basic**	**Focused**	**Enhanced**	**PlyoPulse**		
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	16.64 µC @ 500Ω	48 µC @ 500Ω
Maximum Current Density	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	2.0 mA/cm² @ 500Ω	0.65mA/cm² @500Ω	1.49 mA/cm2 @ 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	N/A	N/A
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	3.46mW/cm² @500Ω	27.6 mW/cm² @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	N/A	N/A
Burst Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Yes	NA
ON Time	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	1 - 12 seconds	6 seconds	6 seconds	6 seconds	4 - 12 seconds	10 seconds	NA
OFF Time	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	1 - 6 seconds	4 seconds	4 seconds	4 seconds	2 - 6 seconds	1 seconds	NA

Performance Data

The following nonclinical performance testing has been conducted to support the performance of the SofWave System. In all instances, the subject SofWave System performed as intended.

- 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, and IEC 60601-2-62;
- Functional bench testing was conducted to verify the minor device modifications did not affect the device performance.

Clinical Summary

No clinical test data was required to support substantial equivalence.

Conclusion

The subject device and its predicate have the same intended use and similar indications, technological characteristics and principles of operation. Moreover, the minor differences in the technological characteristics do not present different questions of safety or effectiveness as compared to the predicate device. Performance testing demonstrates that the subject device is as safe and effective as its predicate device. Thus, the SofWave is substantially equivalent to its predicate device.