August 7, 2024

Sofwave Medical Ltd.
Ruthie Amir
Chief Medical Officer
1 Ha-Otsma St.
Yokneam Ilit, 2069200
Israel

Re: K241685
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: June 11, 2024
Received: June 11, 2024

Dear Ruthie Amir:

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,

Tushar Bansal -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241685

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.
• Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.

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, K241685

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
ruthie@sofwave.com
+972543003164

Date Prepared: June 11, 2024

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 (K240687) (Predicate Device)

Mettler Electronics Corporation's accufit (K233926) (Predicate Device)

Hivox Biotek Inc.'s HIVOX Spopad EMS SP-911, SP-921 (K192264) (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.
- Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.

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) console; 2) applicator; and 3) Electrical Muscle Stimulation (EMS) Module (Pure Impact). The console includes 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 of Technological Characteristics with the Predicate Devices

The SofWave module is almost identical to the previous SofWave device that was cleared in K240687, 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 K240687. No hardware changes were made to the cleared SofWave device's Pure Impact module. The software has been updated to allow the previously cleared plyometric protocol to arms. The Pure Impact module also has similar technology to the accufit predicate device (K233926). 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 arms, thighs, and buttocks. Both the Pure Impact module of SofWave system and accufit consist of a console with a touchscreen control panel and power supply module. For both devices, all system functions are controlled through the console. During a treatment session, one or more electrodes are secured to the patient, and 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	**Predicate Device K240687**
Product	**SofWave (SofWave Module)**	**SofWave (SofWave Module)**
Regulation Number	21 CFR 878.4590	21 CFR 878.4590
Product Code	OHV	OHV
Indications for Use	The SofWave System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial	The SofWave System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial

	Subject Device	Predicate Device K240687
Product	**SofWave (SofWave Module)**	**SofWave (SofWave Module)**
	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.	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.
Device 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 applicator)	3-5 Joule per PZT (Lift and Precise applicators) 2.6-7 Joule per PZT (Smooth 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	Predicate Device (K240687)	Predicate Device (K233926)
Product	**SofWave (Pure Impact Module)**	**SofWave (Pure Impact Module)**	**accufit**
Regulation Number	21 CFR 890.5850	21 CFR 890.5850	21 CFR 890.5850
Classification Name	Powered muscle stimulator	Powered muscle stimulator	Powered muscle stimulator
Product Code	NGX	NGX	NGX
Indication for Use	indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.	indicated to be used for: • Improvement of abdominal tone, for strengthening of the abdominal muscles, for development of firmer abdomen.	• Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increase local blood circulation.

	Subject Device	Predicate Device (K240687)	Predicate Device (K233926)
Product	**SofWave (Pure Impact Module)**	**SofWave (Pure Impact Module)**	**accufit**
	• Improvement of muscle tone and firmness, for strengthening muscles in arms, thighs and buttocks areas.	• Strengthening, toning and firming of buttocks and thighs.	• Muscle re-education • Maintaining or increasing range of motion • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis • 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
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	100-240VAC , 50/60Hz, 1.0A (Fuse: 250V / 6.3A)
Patient Leakage Current - Normal Condition	Normal condition = less than 100µA	Normal condition = less than 100µA	Less than 100µA
Display	Touch screen LCD	Touch screen LCD	Touch screen LCD
Number of Output Channels	Maximum of 4 channels per treatment (up to 2 on arms)	Maximum of 4 channels per treatment	2
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	Double insulated wire non- conductive enclosure
Regulated Current or Regulated Voltage	Regulated current	Regulated current (all channels)	Regulated current

	Subject Device	Predicate Device (K240687)	Predicate Device (K233926)
Product	**SofWave (Pure Impact Module)**	**SofWave (Pure Impact Module)**	**accufit**
Software / Firmware / Microprocessors Controls?	Yes	Yes	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	Yes
Low Battery?	Yes	Yes	Yes
Voltage/Current Level?	Yes (Energy level)	Yes (Energy level)	Yes
Timer Range (minutes)	Up to 60 minutes	Up to 60 minutes	13, 30, 45 minutes
Compliance with Voluntary Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 14971	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 14971	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 14971, UL 60601, CSA C22.2 No 606.1
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	Yes
Housing Material and Construction	PCABS510 for console covers & end point shells	PCABS510 for console covers & end point shells	ABS plastic

Notably, the subject Pure Impact module has very similar output waveform specifications as the accufit predicate device and the HIVOX reference device. As shown in the detailed comparison below, all parameters are similar between the devices. Differences are minor and not clinically relevant.

Table 3: Comparison of Waveform Specifications

	Subject Device				SofWave Pure Impact (K240687)				accufit (K233926)	HIVOX (K192264)
	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	Not publicly available.	Symmetrical biphasic
Shape	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Square wave	Not publicly available.	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%)	Not publicly available.	52-58.4 Vpp @ 500Ω;
	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%)	Not publicly available.	102-106 Vpp @ 2kΩ
	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%)	Not publicly available.	150-154 Vpp @ 10kΩ
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%)	Not publicly available.	104-117 mA pp @ 500Ω (± 20%)
	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%)	Not publicly available.	51-53 mA pp @ 2kΩ (± 20%)
	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%)	Not publicly available.	15-15.4 mA pp @ 10kΩ-15.4 (± 20%)
Pulse Width	250 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 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	Not publicly available.	400 µSec
Frequency	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	1-100Hz @ 500Ω	Not publicly available.	2-25 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	Not publicly available.	Not publicly available.
Phase duration	250 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 µS (± 10%) @500Ω	150 to 350 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	Not publicly available.	N/A
Net charge	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	0 uC @500Ω (Being Biphasic in	Not publicly available.	0.416-0.468 µC @500Ω

	Subject Device				SofWave Pure Impact (K240687)				accufit (K233926)	HIVOX (K192264)
	Basic	**Focused**	**Enhanced**	**PlyoPulse**	**Basic**	**Focused**	**Enhanced**	**PlyoPulse**		
	nature the net charge would be Zero)	nature the net charge would be Zero)	nature the net charge would be Zero)	nature the net charge would be Zero)	nature the net charge would be Zero)	nature the net charge would be Zero)	nature the net charge would be Zero)	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	Not publicly available.	41.6-46.8 µC, 500 Ω
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	Not publicly available.	1.057-1.672 mA/cm2, 500 Ω
	*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	Not publicly available.	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	Not publicly available.	0-0671-0.0869 Watt/cm², 500 Ω
	*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	Not publicly available.	N/A
Burst Mode	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Not publicly available.	Yes for one configuration, not for the other
ON Time	6 seconds	6 seconds	6 seconds	4 - 12 seconds	6 seconds	6 seconds	6 seconds	4 seconds	Not publicly available.	N/A
OFF Time	4 seconds	4 seconds	4 seconds	2 - 6 seconds	4 seconds	4 seconds	4 seconds	2 seconds	Not publicly available.	N/A

Performance Data

Performance testing, including design verification testing and electrical safety testing, confirmed the minor changes in the SofWave module did not raise different questions. The software modifications were evaluated through software verification testing, which was completed successfully with no major issues found. In all instances, the subject SofWave System performed as intended.

Clinical Summary

No clinical test data was used to support the decision of substantial equivalence.

Conclusion

SofWave has the same general intended use and similar indications for use and technological characteristics as the predicate device. The addition of arms to the Pure Impact indications for use and minor technological differences between the subject and the predicate devices do not raise different questions of safety or effectiveness. Performance testing has demonstrated that the device performs as intended. Thus, the SofWave System is substantially equivalent.