December 16, 2022

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

Re: K223237
Trade/Device Name: SofWave System
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System For Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: October 19, 2022
Received: October 19, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K223237

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 regions for subjects aged 22 and older. The SofWave System is also intended for short-term improvement in the appearance of cellulite.

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

K223237

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

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

Submission Correspondent:

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(267) 675-4611

Date Prepared: December 15, 2022

Name of Device:

SofWave System

Common or Usual Name:

Focused Ultrasound Stimulator System for Aesthetic Use

Classification Name:

21 CFR 878.4590 (Ultrasound for Tissue Heat or Mechanical Cellular Disruption), Class II, product code OHV

Predicate Devices

Sofwave Medical's SofWave System (K211483) (Predicate Device)

Soliton Inc.'s Rapid Acoustic Pulse (RAP) Device (K201801) (Predicate 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 regions for subjects aged 22 and older. The SofWave System is also intended for short-term improvement in the appearance of cellulite.

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 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.

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 K211483, except minor hardware and software changes, which do not significantly affect clinical functionality or performance specifications of the device, and have been verified and tested. The treatment parameter or energy specification of the device remain identical to that cleared in K211483. The purpose of this 510(k) notification is to expand the indications for use to include short-term improvement in the appearance of cellulite. This additional indication for use does not require any additional hardware or software changes to the device.

The subject SofWave device is also similar to the Soliton RAP predicate device (K201801) that is indicated for short-term improvement in the appearance of cellulite. Both devices are comprised of a console and a treatment applicator. Both devices deliver acoustic energy into the skin to alter the structure of the tissue, resulting in improved appearance of cellulite. The minor differences in the technology do not raise different questions of safety or effectiveness. For both devices, the same types of safety and efficacy questions arise. Clinical testing further demonstrates the performance of the SofWave device, showing that the magnitude of the clinical effects with treatment is comparable between SofWave and the Soliton RAP device.

SofWave System Substantial Equivalence Chart

	Sofwave Medical's SofWave System **(Subject Device)**	**Sofwave Medical's SofWave System (K211483)** **(Predicate Device)**	**Soliton RAP for Cellulite (K201801)** **(Predicate Device)**
Regulatory Class	II	II	II
CFR Regulation	21 CFR 878.4590	21 CFR 878.4590	21 CFR 878.4810
Product Code	OHV	OHV	GEX
Intended 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 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 Rapid Acoustic Pulse Device (RAP) is indicated for use as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. The RAP device is also intended for short-term improvement in the appearance of cellulite.
Device Technology	High intensity, non-focused ultrasonic pulse that can be delivered percutaneously to tissues to reduce fibrous septa's tendency to deform the skin surface	High intensity, non-focused ultrasonic pulse that can be delivered percutaneously to tissues	Acoustic pulse that partially disrupts the fibrous septa to improve cellulite appearance.
Type of Energy	High intensity therapeutic ultrasound	High intensity therapeutic ultrasound	Acoustic shockwave
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	• Console that includes the power sources, electrical components and user interface (touchscreen) • Handpiece
Energy Type	High Intensity non-focused Ultrasound	High Intensity non-focused Ultrasound	Broadband/Ultrasonic
Treatment Depth	1-2 mm	1-2 mm	1-10 mm*
Tissue at Focal Point Temperature	60°C -70°C	60°C -70°C	N/A
Thermal Energy Output per channel	< 5J per channel	< 5J per channel	N/A
Thermal Coagulation Point	Confined to focal zone; shallow (<3 mm); no thermal coagulation below focal zone	Confined to focal zone; shallow (<3 mm); no thermal coagulation below focal zone	N/A
Epidermal Impact	Non-invasive; Cooling required	Non-invasive; Cooling required	Non-invasive

	Sofwave Medical's SofWave System **(Subject Device)**	**Sofwave Medical's SofWave System (K211483)** **(Predicate Device)**	**Soliton RAP for Cellulite (K201801)** **(Predicate Device)**
Transducer Acoustic Core	Energizer comprises: - Array of piezoelectric ceramic plates (7 x 5 mm^2) - Temperature control unit (thermistors, Thermoelectric cooler (TEC), Heat Exchanger)	Energizer comprises: - Array of piezoelectric ceramic plates (7 x 5 mm^2) - Temperature control unit (thermistors, Thermoelectric cooler (TEC), Heat Exchanger)	Cartridge is comprised of electrodes immersed in the circulating saline
Frequency	10 MHz – 12 MHz	10 MHz – 12 MHz	N/A
Treatment Area Width	35mm	35mm	38mm
Peak Acoustic Pressure	1.2 MPa	1.2 MPa	0.25 to 12 MPa
User Interface	LCD Touch Screen Graphic User Interface	LCD Touch Screen Graphic User Interface	LCD Touch Screen Graphic User Interface
Electrical Safety/EMC	IEC 60601-1 Compliant IEC 60601-1-2 Compliant	IEC 60601-1 Compliant IEC 60601-1-2 Compliant	IEC 60601-1 Compliant IEC 60601-1-2 Compliant
Input Power	100-240VAC 60Hz 10A	100-240VAC 60Hz 10A	240VAC 60Hz 15A

* Based on publicly available information for Soliton

Performance Data

The following nonclinical performance testing has been conducted to support the substantial equivalence of the SofWave System to its predicate device, consistent with FDA's "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use" (2011). 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
- 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, and IEC 60601-2-62
- Functional bench testing was conducted to verify that the modifications to the device did not affect the device performance

To support the expansion of indications for cellulite, the company conducted a clinical study that evaluated the safety and effectiveness of the device for the non-invasive dermatological aesthetic improvement in cellulite appearance. A total of 69 subjects were enrolled and 68 subjects were treated at 4 sites in the United States.

Eligible patients received 2 treatments (2-4 weeks apart) using the SofWave System on one side (right or left) of the lateral / posterior upper thigh or buttocks. Serial clinical photographs were

collected under standardized conditions before treatment (baseline) and at the 3-month follow-up visits. Photographs were assessed by blinded independent reviewers to identify pre-treatment images when compared to post treatment images and to grade the pre-treatment and post-treatment images using the Cellulite Severity Scale (CSS). Improvement was also evaluated using the Global Aesthetic Improvement Scale (GAIS) and Laxity Scale (LS). Safety assessments included evaluation of AEs via physician examination during and after the treatment.

The blinded reviewers correctly identified the post treatment images for 89% of the subjects. Throughout the study, there was only one adverse event reported, which was not related to the device. No serious or unanticipated adverse event was reported during the study. The mean pain level was 4.6 (moderate pain). Based on a literature review, the study results were consistent with the predicate device.

Conclusion

SofWave has the same general intended use and similar indications, technological characteristics, and principles of operation as the company's previously cleared SofWave System (K211483) and Soliton's RAP device (K201801) ("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.