March 14, 2023

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

Re: K230019
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: January 3, 2023
Received: January 3, 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 (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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.14 15:49:19 -04'00'

Mark W. Trumbore, 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)*

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

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: March 3, 2023

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 Device

Sofwave Medical's SofWave System (K223237) (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 device. The primary modification is the addition of a smaller applicator to the existing larger applicator. The main difference between the small applicator and the previously cleared large applicator is that the small applicator has 3 piezoelectric ceramic plates (PZTs), compared to 7 PZTs in the existing large applicator. A small applicator is being added to is designed to allow the user treatment flexibility and easier access to smaller and more curved areas. While it covers a smaller area for each pulse due to fewer PZTs than the large applicator, for a given area to be treated, the total energy received is similar regardless of the choice of applicators. The addition of the small applicator does not require changes of hardware or energy parameters for the console. Performance testing, including bench, electrical, biocompatibility, software, and animal testing, demonstrated that the device with the additional small applicator performs similarly as the predicate device.

Other than the addition of the small applicator, the subject SofWave device is almost identical to the previous SofWave device that was cleared in K223237. The minor changes do not significantly affect clinical functionality or performance specifications of the device, and have been verified and tested.

Thus, the subject SofWave device has similar technological characteristics as its predicate device.

	Sofwave Medical's SofWave System **(Subject Device)**	**Sofwave Medical's SofWave System** **(K223237)** **(Predicate Device)**
Regulatory Class	II	II
CFR Regulation	21 CFR 878.4590	21 CFR 878.4590
Product Code	OHV	OHV
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 SofWave System 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 to reduce fibrous septa's tendency to deform the skin surface
System components	• Console that includes the power sources, electrical components and user interface (touchscreen) • Handpiece (large and small)	• Console that includes the power sources, electrical components and user interface (touchscreen) • Handpiece (large)
Energy Type	High Intensity non-focused Ultrasound	High Intensity non-focused Ultrasound
Treatment Depth	1-2 mm	1-2 mm
Tissue at Focal Point Temperature	60°C -70°C	60°C -70°C

	Sofwave Medical's SofWave System **(Subject Device)**	**Sofwave Medical's SofWave System** **(K223237)** **(Predicate Device)**
Energy Delivered Per Channel	3-5 Joule per PZT	3-5 Joule per PZT
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
Epidermal Impact	Non-invasive; Cooling required	Non-invasive; Cooling required
Transducer Acoustic Core	Energizer comprises: - Array of piezoelectric ceramic plates (7 x 5 mm^2 or 3 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)
Frequency	10-12 MHz	10-12 MHz
Treatment Area Width	Precise (small) applicator: 3PZT x 5mm^2 = 15 mm^2 Lift (large) applicator: 7PZT x 5mm^2 = 35 mm^2	35 mm^2
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
Input Power	100-240VAC 60Hz 10A	100-240VAC 60Hz 10A

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 addition of the small applicator did not affect the device performance
- In vivo testing in an animal model was performed to evaluate and establish the safety and effectiveness of the subject device The preclinical, acute, in vivo study using a porcine model was designed to assess the histological tissue thermal effects and coagulative zones created by the SofWave system while using the small applicator (Precise applicator) across a range of treatment settings. Histopathology evaluation of coagulation areas was performed by a third-party expert reviewer blinded to the treatment setting.

Conclusion

The subject SofWave System and its predicate have the same indications and principles of operation, and similar technological characteristics. 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. The in vivo study using a porcine model shows the new small applicator has substantially equivalent thermal effect to the larger applicator of the previously cleared SofWave System (K223237). Thus, the subject SofWave System is substantially equivalent to its predicate device.