November 15, 2021

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

Re: K211483
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 14, 2021
Received: October 14, 2021

Dear Mrs. 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,

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: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*
K211483

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.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY
Sofwave Medical's SofWave System

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

Sofwave Medical Ltd.
Beit Tavor 2
Yokneam Ilit,
Israel 2069202

Submission Correspondent:

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

Date Prepared: November 9, 2021

Name of Device (Trade Name)

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

Ulthera, Inc.'s Ulthera® System (K180623) (Predicate device)

Sofwave Medical's Sofacia System (K191421) (Reference device)

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.

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 its predicate device, the Ulthera System (K180623). Both the subject device and the predicate device consist of a console that includes the power sources, electrical components, user interface (touchscreen), a cart for storage of system components, and a handpiece that is connected to a transducer.

The technological characteristics of the console of the subject device and the predicate device are similar. The console of both the subject and predicate device are assembled in a mobile cart that comprises of a control unit (or personal computer (PC)) with a touchscreen monitor and Graphical User Interface (GUI). The control unit of both the subject and predicate device allow the operator to adjust the treatment settings, view the system status and receive maintenance notices, fault and safety alerts. Further, the main processor of both the subject and predicate device control and monitor all system components. The computers for both systems receive input from the user via the user interface where treatment parameters can be adjusted accordingly. During the treatment, relevant information is displayed on the screen for both the subject and predicate device such as the operating conditions, equipment activation status, treatment parameters, system messages and prompts, and ultrasound images. Further, both the subject and predicate device consist of a main board that includes all electronic circuits required for operating the system.

Both the subject device and predicate device consist of software that enables the continuous monitoring of the overall applicator and console to ensure safe usage. The software for both devices monitors various parameters including operating conditions, equipment activation status, treatment parameters, system messages and prompts.

The technological characteristics of the applicator of both the SofWave System and the predicate device are also similar. The applicator of both the subject and predicate device are comprised of ultrasonic transducers that emit continuous acoustic waves and is connected by a flexible cable (umbilical cord) connecting the handle to the control unit (console). The thermal coagulation point of both the subject device and predicate device are similar (confined to a focal zone which is <3mm for the subject device as compared to 5mm for the predicate device).

In addition, the treatment depth of the subject device is similar to the predicate device. Although the subject device consists of a thermoelectric cooler (TEC) that maintains the epidermis at a cool temperature whereas the predicate does not have this technology, this difference does not raise new questions of safety or effectiveness as the cooling of the subject device provides additional protection to the epidermis from the spread of heat from the dermis.

The SofWave System also has the same technological characteristics compared to its reference device, the previously cleared Sofacia System (K191421). Although the subject device has some minor modifications to the technological characteristics, these modifications do not raise new questions of safety or effectiveness because they do not change the device's principles of operation.

In sum, the subject SofWave System has the same or very similar technological characteristics compared to its predicate and reference devices, and the minor differences do not raise new types of safety and effectiveness questions.

	Subject Device Sofwave Medical's SofWave System	Predicate Device Ulthera, Inc.'s Ulthera® System (K180623)	Reference Device Sofwave Medical's Sofacia System (K191421)
Regulatory Class	II	II	II
CFR Regulation	21 CFR 878.4590	21 CFR 878.4590	21 CFR 878.4590
Product Code	OHV	OHV, IYO	OHV
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 Ulthera System is indicated for use as a non-invasive dermatological aesthetic treatment to: • lift the eyebrow • lift lax submental (beneath the chin) and neck tissue; which can also affect the appearance of lax tissue in the submental and neck regions improve lines and wrinkles of the décolleté The Ulthera System in conjunction with the Ulthera DeepSEE transducer allows for ultrasonic visualization of depths up to 8 mm below the surface of the skin. The indicated use of the imaging is to visualize the dermal and subdermal layers of tissue to: • ensure proper coupling of the transducer to the skin (current cleared indication) • confirm appropriate depth of treatment such as to avoid bone	The Sofacia System is indicated for use as a non-invasive dermatological aesthetic treatment to improve facial lines and wrinkles for subjects aged 22 and older.
Treatment Depth	1-2 mm	4.5 mm 3 mm 1.5 mm	1-2 mm

	Subject Device Sofwave Medical's SofWave System	Predicate Device Ulthera, Inc.'s Ulthera® System (K180623)	Reference Device Sofwave Medical's Sofacia System (K191421)
Tissue at Focal Point Temperature	60°C -70°C	65°C	60°C -70°C
Type of Energy	Thermal < 5J per channel or high intensity therapeutic ultrasound	Thermal < 2J	Thermal < 5J per channel or high intensity therapeutic ultrasound
System components	- Console that includes the power sources, electrical components and user interface (touchscreen). - Handpiece that includes the transducer - Cart for storage of system components	- Console that includes the power sources, electrical components and user interface (touchscreen). - Handpiece - Three different transducers - Cart for storage of system components	- Console that includes the power sources, electrical components and user interface (touchscreen). - Handpiece that includes the transducer - Cart for storage of system components
Thermal Coagulation Point	Confined to focal zone; shallow (<3 mm); no thermal coagulation below focal zone	Confined to focal zone; shallow (<5 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 not required	Non-invasive; Cooling required
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: - Focused ultrasonic transducer with a dome-shaped design, moving on a mechanical axis	Energizer comprises: - Array of piezoelectric ceramic plates (7 x 5 mm^2) - Temperature control unit (thermistors, Thermoelectric cooler (TEC), Heat Exchanger)
Energy Type	- High Intensity Ultrasound - Thermal	- High Intensity Ultrasound - Thermal	- High Intensity Ultrasound - Thermal
Frequency	10 MHz – 12 MHz	4 MHz-10 MHz	10 MHz – 12 MHz
Electrical requirements	100-240 VAC; 10 A; 50-60Hz; single phase	100-240 VAC; 2.5 A; 50-60 Hz; single phase	100-240 VAC; 10 A; 50-60Hz; single phase
Treatment Area Width	35mm	25mm	35mm

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: 2014, IEC 60601-1: 2005 (R) 2012 , IEC 60601-1-6: 2010 (R) 2013, and IEC 60601-2-62: 2013
- Ultrasound energy safety was established in accordance with IEC 60601-2-62: 2013
- Functional bench testing was conducted to verify the device performance (acoustic mapping and parameter measurement testing, applicator performance testing, handle acoustic emission measurements, transducers linearity experiment, power control and output, cooling power, etc.)
- In vivo testing in an animal model was performed to evaluate and establish the safety and effectiveness of the subject device

To support the expansion of indications, the Company conducted a clinical study that evaluated the safety and effectiveness of the device for the non-invasive dermatological aesthetic treatment to lift the eyebrow and lift lax submental and neck tissue. A total of 92 subjects were enrolled and 80 subjects were treated at 5 investigational sites in the United States. Each subject was treated on 3 face and neck zones including the forehead and temples for eyebrow lifting (Zone 1), the cheeks (Zone 2), and the submental and the neck (Zone 3). Overall, 467 facial areas were treated during the study course.

For Zone 1, the co-primary effectiveness endpoints were the independent masked evaluators' correction identification of pre-post image sequence for eyebrow lift, and the objective measurement of maximal eyebrow lift according to quantitative 2D imaging. The results demonstrate that the blinded reviewers identified correctly the pre- and post-treatment photographs for 79% (53/67) of the treated subjects (based on the agreement of two blinded reviewers). Objective measurement of eyebrow lift by quantitative 2D imaging demonstrated an average lift of 0.78 mm for maximal eyebrow height (MEH) and 0.69 mm for average eyebrow height (AEH). Therefore, both co-primary endpoints are met. With regard to the secondary endpoints, progressive improvement was noticed along the study course and 80% (51/64) of subjects were improved based on Physician Global Aesthetic Improvement Scale (PGAIS) assessment at the 3-month follow-up visit.

For Zone 3, the co-primary effectiveness endpoints were the independent masked evaluators' correction identification of pre-post image sequence for submental lift, and the objective measurement of lax submental and neck tissue lift according to quantitative 2D imaging. The results demonstrate that the blinded reviewers identified correctly the pre- and post-treatment photographs for 80% (60/75) of the treated subjects (based on the agreement of two blinded reviewers). Objective measurement of lax submental and neck tissue lift by quantitative 2D imaging demonstrated an average lift of 38 mm^2. Therefore, both co-primary endpoints are met. With regard to the secondary endpoints, progressive improvement was noticed along the study course and 85% (61/72) of subjects were improved based on Physician Global Aesthetic Improvement Scale (PGAIS) assessment at the 3-month follow-up visit.

The patient satisfaction questionnaire demonstrated that 55% of subjects reported improvement and satisfaction for the eyebrow lift. For the question, would you undergo further treatments, 37/64 (58%) said yes. 14/64 (17%) replied no and 13/64 (20%) replied not sure. 55% of subjects reported improvement for submental and neck lift. 50% of subjects reported satisfaction. For the question, would you undergo further treatments, 43/72 (60%) of subjects said yes. 14/72 (19%) subjects said no and 15/72 (21%) subjects said not sure.

The clinical study also demonstrated a favorable safety profile for the SofWave for the proposed use in eyebrow lift and lax submental and neck tissue lift. Throughout the study, only one device related adverse events were reported, which was moderate, transient, and resolved completely with topical cream only. No serious or unanticipated adverse event was reported during the study. The mean pain level during treatment was 6.4 out of 10 for Zone 1 and 5.3 out of 10 for Zone 3. Based on a literature review, the study results were consistent with the predicate device.

Conclusions

The SofWave System has the same intended use and similar indications for use as its predicate device, Ulthera System. Further, the SofWave System has very similar technological characteristics and principles of operation as its predicate device, Ulthera System. 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.