December 22, 2023

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

Re: K233104
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: September 26, 2023
Received: September 26, 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 (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,

Francisco Delgado -S
2023.12.22 09:25:16 -05'00'

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)*
K233104

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 and the treatment of acne scars. The SofWave System is indicated to improve the appearance of skin laxity on the upper arms.

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: November 28, 2023

Name of Device

SofWave System

Common or Usual Name

Focused Ultrasound Stimulator System for Aesthetic Use

Classification Name

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

Predicate Device

SofWave Medical's SofWave System (K231537)

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, IoT, 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.

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 and the treatment of acne scars. The SofWave System is indicated to improve the appearance of skin laxity on the upper arms.

Comparison of Technological Characteristics with the Predicate Device

The SofWave System has similar technological characteristics compared to the predicate device. The subject SofWave device is almost identical to the previous SofWave device that was cleared in K231537, except minor hardware and software changes that do not significantly affect clinical functionality or performance specifications of the device and have been verified and tested. The treatment parameters or energy specifications of the device remain identical to those cleared in K231537. The purpose of this 510(k) notification is to expand the indications for use to include improvement of the appearance of skin laxity on the upper arms. This additional indication for use does not require any additional hardware or software changes to the device.

	Subject device: **SofWave System**	**Predicate device:** **SofWave System (K231537)**
Regulation	878.4590	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 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.
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

	Subject device: SofWave System	Predicate device: SofWave System (K231537)
Energy delivered / fluence	3-5 Joule per PZT (or 6-10 J/cm^2)	3-5 Joule per PZT (or 6-10 J/cm^2)
Epidermal impact	Non-invasive	Non-invasive
Treatment area	15 or 35 mm^2	15 or 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	100-240 VAC, 60Hz, 10A	100-240VAC, 60Hz, 10A

Performance Data

Nonclinical Testing

The following nonclinical testing was conducted to support substantial equivalence of the SofWave System to its predicate device. In all instances, the SofWave System functioned as intended.

- Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993-1.
- Software verification and validation was performed and demonstrated that the software performs as intended.
- Electrical safety and electromagnetic compatibility were 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.

Clinical Testing

To support the expansion of the device's indications for use, a single arm, prospective, self-controlled, multicenter study was conducted to evaluate the SofWave device for improving the appearance of skin laxity on the upper arms. A total of 46 subjects were enrolled and treated on both upper arms at 4 sites in the United States. Subjects attended 2 treatment sessions (1-3 weeks apart) and a follow-up visit 3 months after the final treatment visit.

The primary efficacy evaluation found that 93% of treated arms showed improvement in upper arm skin laxity, as assessed by the correct identification of the pre- and post-treatment photographs by at least 2 of 3 blinded reviewers. Consistent with the results for the primary efficacy endpoint, the secondary efficacy endpoint results also supported device effectiveness for the expanded indications for use. As assessed by the blinded reviewers, on average the treated arms improved from severe skin laxity at baseline to moderate skin laxity after treatment, based on a 5-point upper arm skin crepiness/laxity grading scale. Additionally, 93% of the treated arms were improved or very much improved in appearance, as rated by the blinded reviewers using the Global Aesthetic Improvement Scale.

The clinical study also demonstrated a favorable safety profile for the SofWave System for use in improving the appearance of skin laxity on the upper arms. Throughout the study, there were no device-related adverse events. Anticipated tissue responses mostly consisted of erythema and edema that resolved spontaneously after treatment. Most subjects reported none to mild levels of pain during treatment and no discomfort afterward, further confirming that the device was well-tolerated.

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 (K231537). The minor technological differences between the subject and the predicate device 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.