November 3, 2023

Classys Inc
% Parul Chansoria
Founder and CEO
Elexes Medical Consulting, LLC
30 N Gould St Ste R
Sheridan, Wyoming 82801

Re: K230100
Trade/Device Name: SCIZER (SC1-M410)
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System For Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: October 4, 2023
Received: October 4, 2023

Dear Parul Chansoria:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.11.03 13:43:38 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K230100

Device Name
SCIZER (SC1-M410)

Indications for Use *(Describe)*
The SCIZER delivers high intensity focused ultrasound (HIFU) energy that can disrupt subcutaneous adipose tissue(SAT) to provide a non-invasive approach to achieve a desired aesthetic effect.
The SCIZER is specifically indicated for non-invasive waist circumference reduction.

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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5.1. Submitter's Information

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Date Prepared: November 03, 2023

5.2. Device Information

Trade name/Model No: SCIZER (SC1-M410)
Classification name: Focused Ultrasound for Tissue Heat or Mechanical Cellular Disruption
Regulatory class: Class II
Classification panel: General and Plastic Surgery
Regulation name: Focused ultrasound stimulator system for aesthetic use
Product code: OHV
Regulation number: 21CFR878.4590

5.3. Predicate Device Information

The Predicate Device for SCIZER (SC1-M410), hereafter referred to as the Subject Device is listed in Table 1.

Table 1 - Predicate Device identification

Predicate Device Name	Manufacturer	510K Number
LipoSonix® system model 2	Solta Medical Inc.	K112626

5.4. Device Description

The Subject Device consists of 2 handpieces, a control unit, a Touch LCD monitor, power supply unit for irradiation and for setting parameters after the main power and key switch is turned on.

HIFU energy is irradiated based on a linear scanning method through the handpiece depending on irradiation energy that is set in advance by the user. The Cartridge D13 used with the Subject Device focuses the HIFU energy from the transducer onto the fat layer at a depth of 13mm from the surface of the skin. The Cartridge can treat a region of tissue up to 46mm long and 46mm wide. The Cartridge can apply a maximum of 24 lines at a time. As a result, tissue temperature rises over 56°C and thermal coagulation occurs. Using thermal effects generated by the HIFU transducer, cellular disruption of the subcutaneous adipose tissue occurs. This thermal coagulation results in the contraction of the collagen and subsequently results in the destruction of the adipose tissue. The destroyed adipose tissue is cleared via an inflammatory response.

Immediately before the procedure, purified water was applied to the treatment area to promote the desired energy transmission of the ultrasound transducer. To minimize the pain from the thermal HIFU procedure, the cooling level was used through the GUI. It is recommended to use an ultrasound imaging system to visualize the sub-dermal regions of interest before treatment. It allows the physician to compile a precise view of the target treatment area.

5.5. Indications for Use

The SCIZER delivers high intensity focused ultrasound (HIFU) energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect.

The SCIZER is specifically indicated for non-invasive waist circumference reduction.

5.6. Comparison of Technological Characteristics with the Predicate Device

Table 2 - Substantial equivalence comparison

Parameters	Subject Device SCIZER (SC1-M410)	Predicate Device LipoSonix® system model 2	Remarks
Output Energy	HIFU Energy	HIFU energy	Equivalent

Frequency of Ultrasound output	2 MHz	2 MHz	Equivalent
Maximum power delivered to the patient	60 J/cm^2	60 J/cm^2	Equivalent
Cartridge Focal length	13 mm	13 mm	Equivalent
Treatment line	24 line	24 line	Equivalent
Treatment line/sec	20.50 mm/sec	20.19 mm/sec	Different
Space between each treatment line	2 mm	2 mm	Equivalent
Treatment area	46 x 46 (mm)	46 x 46 (mm)	Equivalent
Treatment time	60 minutes	60 minutes	Equivalent

5.6.1. Similarities

- The intended use is equivalent for the Subject Device and Predicate Device. Both devices belong to the same Regulatory class and both are Prescription Devices.
- The technological characteristics such as the Energy Source, Frequency of HIFU energy, Maximum power delivered to the patient, and Cartridge Focal length are equivalent for both the Subject Device and Predicate Device.
- The treatment line is equivalent as that of the Predicate Device.
- The spacing between each line is equivalent for both the Subject Device and Predicate Device.
- The treatment area is equivalent for both the Subject Device and Predicate Device.
- The total treatment time is equivalent for both the Subject Device and Predicate Device.

5.6.2. Differences

- Treatment line/sec is different for both the Subject Device and Predicate Device.

The differences between the Subject Device and the Predicate Device do not raise new questions of safety and efficacy. Testing conducted by Classys Inc. demonstrates that the Subject Device performs as intended.

5.7. Performance data

5.7.1. Electrical safety and Electromagnetic compatibility (EMC)

Electrical safety, and EMC was evaluated the Subject Device and complies with the following standards:

- IEC 60601-1:2005, AMD:2012, Edition 3.1
- IEC 60601-1-2 Edition 4.0 2014-02

5.7.2. Performance testing

Acoustic power testing, Beam Profile testing, Thermal Evaluation testing, and Focal length were performed according to Design Requirement specification, Verification, and Validation plans. The device complies with the following standards:

- IEC 60601-2-62 Edition 1.0 2013-07
- IEC 62555 Edition 1.0 2013-11

All test results were satisfactory with no deviations from the applicable standards or protocols.

5.7.3. Biocompatibility testing

Biocompatibility testing in accordance with ISO 10993 for skin irritation, sensitization, and cytotoxicity testing supported the biocompatibility of the patient-contacting components of the device.

- ISO 10993-5 Third Edition 2009-06-01
- ISO 10993-10 Fourth edition 2021-11
- ISO 10993-23 First edition 2021-01

5.7.4. Software Verification and Validation Testing:

Software Verification and Validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered a 'Moderate' level of concern.

5.8. Animal Study

Animal Testing was conducted for evaluating the effectiveness of the Subject Device in comparison to its Predicate Device, by comparing the tissue damage, the temperature increases at the point of contact, and subcutaneous fat reduction in an animal model were performed and the test results support the substantial equivalence.

5.9. Clinical study

CLASSYS Inc. conducted a single-centered, single group, parallel clinical study with 20 study participants aged between 18 and 65 years. The study evaluated the safety and effectiveness of the Subject Device.

Efficacy outcome

The primary efficacy outcome was assessed in terms of waist circumference reduction above 2.45 cm after two sets of treatments/procedures. The treatments using the Subject Device were performed on 12 sites of the abdomen, with a cumulative energy of 150 J/cm2 and 135 J/cm2, during the 1st set and 2nd set of treatments, and were based on the umbilicus of each subject. The second procedure was executed at the 4th week after the 1st procedure and on the same sites of the participants. During the application of treatment sets, each procedure site received 3 passes within a maximum of 20 minutes. Data acquired from the subjects of this study were evaluated by FAS (Full analysis Set) and PPS (Per-Protocol Set). Additionally, Investigator Analysis Set (IAS) was added as an analysis group. The evaluation of primary efficacy outcome was done by testing the null hypothesis ($D<=\delta$), in which paired t-test or Wilcoxon's signed-rank test were used to compare the difference (D) in the waist circumference between the 2 time points (measurement prior to the 1st procedure and measurement at the 16th week) with the reference value of 2.45cm (δ) using one-tailed testing at a significance level of 2.5%. All 3 sets revealed a statistically significant difference in the waist circumference between the 8th week and prior to the 1st procedure.

The secondary efficacy outcomes comprised evaluation of the waist-hip ratio(%), changes in weight, changes in subcutaneous fat layer thickness using ultrasound, changes in the abdominal fat thickness using Caliper, changes in the area of abdomen fat and the height of the subcutaneous fat area measured through abdomen fat CT, and evaluation of abdominal subcutaneous fat reduction on procedure site using GAIS.

The evaluation was conducted by two-tailed testing at a significance level of 5% and a statistically significant decrease was observed at each evaluation time compared to measurements taken before the 1st procedure.

The reduction of waist circumference was assessed using Global Aesthetic Improvement scale (GAIS) by three independent investigators (IGAIS) and by the Subjects (SGAIS).

The Investigator Global Aesthetic Improvement Scale (IGAIS) evaluations were conducted prior to the 2nd treatment and 4 weeks after the 2nd treatment, both for the FAS set, PPS set, and the IAS set. The evaluations for each of the three sets demonstrated a statistically significant (p=0.000) difference for the mean±standard deviations in the two time points (FAS= 0.75±0.44, 0.89±0.54; PPS= 0.76±0.46, 0.74±0.47; IAS=0.83±0.41, 0.90±0.51). All three independent evaluators observed a decrease in waist circumference during these evaluation periods.

Similarly, the Subject Global Aesthetic Improvement Scale (SGAIS) evaluations were conducted at six different time points, where all demonstrated a statistically significant difference for the mean±standard deviations, compared to the evaluation before the 1st procedure.

Evaluation of safety

Evaluation of safety was conducted through blood test, evaluation of pain (NRS scale), and incidence of adverse events during the clinical trial. The results from blood test results demonstrated that all test items showed values of normal range with no clinically significant abnormalities or differences among the results of each test item.

These results for pain evaluation demonstrated that pain experienced initially after each treatment was resolved completely at 2 weeks from the end of the 2nd treatment.

Throughout the study, no serious or unanticipated adverse events were reported.

Conclusion

The results of the primary efficacy outcome support the Subject Device's effectiveness in terms of waist circumference reduction in a substantially similar manner to that of the Predicate Device. The results from the safety evaluation demonstrate that the Subject Device is equivalent to the predicate in terms of safety. Thus, in entirety, the clinical data demonstrates that the Subject Device is substantially equivalent to the Predicate Device for requested indications for use.

5.10. Conclusion

Subject Device has some technological differences to compare to the predicate LipoSonix® system model 2. Performance test data including the clinical data demonstrates that the Subject Device is substantially equivalent to the Predicate Device in terms of safety and effectiveness for the requested indications for use.