October 18, 2019

Jeisys Medical, Inc.
% Parul Chansoria
Regulatory Consultant
Elexes Medical Consulting
6494 Tralee Village Dr.
Dublin, California 94568

Re: K181896
Trade/Device Name: LIPOcel
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System for Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: September 19, 2019
Received: September 19, 2019

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 (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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.10.18 10:39:16 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181896

Device Name
LIPOcel

Indications for Use *(Describe)*
The LIPOcel delivers High Intensity Focused Ultrasound (HIFU) energy that can disrupt the Subcutaneous Adipose Tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. The LIPOcel 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

I. SUBMITTER

Jeisys Medical Inc.,
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Seoul, Republic of Korea

Contact Person:
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Summary Prepared: July 10, 2018

FDA Establishment registration number: 3006985163

II. DEVICE

Common/Usual Name: Focused Ultrasound Stimulator System for Aesthetic Use
Trade Name: LIPOcel
Regulation Name: Focused Ultrasound Stimulator System for Aesthetic Use Regulatory
Class: Class II
Classification Panel: General and Plastic Surgery Devices
Product Code: OHV
Regulation Number: 21 CFR 878.4590

III. PREDICATE DEVICE

The LIPOcel is substantially equivalent to the following cleared device:

Table 1: Predicate Device

Company	Product	510(k) Number
Solta Medical Inc.	LipoSonix System Model 2	K112626

IV. DEVICE DESCRIPTION

LIPOcel, the Subject Device, is a medical device indicated for non-invasive waist circumference reduction. It consists of a control unit, Touch LCD monitor, power supply unit, and driver unit for irradiation and for setting parameters after the main power and key switch is turned on. The ultrasound energy that is generated from the pulse generator operates the HIFU transducer, and is irradiated from the cartridge when the footswitch or the finger switch on the handpiece is pressed in the READY state and the energy is delivered into the target tissue. HIFU energy is irradiated

based on linear scanning method through the hand-piece depending on irradiation energy, irradiation spacing and irradiation distance, that are set in advance by the user. The Subject Device's L13 Cartridge uses the focused ultrasound energy to focus from the transducer onto the fat layer at a depth of 13mm from the surface of the skin. As a result, tissue temperature rises over 55°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 destruction of the adipose tissue. The destroyed adipose tissue is cleared via an inflammatory response.

V. INDICATIONS FOR USE

The LIPOcel delivers High Intensity Focused Ultrasound (HIFU) energy that can disrupt the Subcutaneous Adipose Tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. The LIPOcel is specifically indicated for non-invasive waist circumference reduction.

VI. TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The key technological characteristics, such as the energy type and the operating principle of the Subject Device are equivalent to that of the Predicate Device. Also, the Subject and Predicate Device have similar indications for use. The only differences between them are the treatment area and the treatment line numbers.

Table 2: Basic Technology Comparison

Parameter	**Subject Device LIPOcel**	**Predicate 1 LipoSonix System Model 2**	**Remark**
Energy Source	HIFU energy	HIFU energy	Same as the Predicate Device
Frequency of Ultrasound energy	2 MHz	2 MHz	Same as the Predicate Device
Maximum power delivered to the patient	60 J/cm^2	60 J/cm^2	Same as the Predicate Device
Cartridge Focal length	13 mm	13 mm	Same as the Predicate Device
Duty Rate	50 %	50%	Same as the Predicate Device
Treatment line	16 line	24 line	Different.

			This difference does not affect the safety and efficacy of the device.
Treatment line/sec	20.19 mm/sec	20.19 mm/sec	Same as the Predicate Device
Space between each line	2 mm	2 mm	Same as the Predicate Device
Treatment area	30 x 30 (mm)	46 x 46 (mm)	Different. This difference does not affect the safety and efficacy of the device.
Treatment Time	60 min	60 min	Same as the Predicate Device

VII. NON-CLINICAL STUDY

Electrical, mechanical, and performance testing were performed in accordance with IEC 60601-1:2005 + AMD1:2012/ EN 60601-1:2006 + A1:2013, IEC 60601-1-2:2007/ EN 60601-1-2:2007, IEC 60601-1-6:2010 + AMD1:2013/ EN 6061-1-6:2010 + A1:2015, IEC 60601-2-62:2013/ EN 60601-2-62:2015, and IEC 62555:2013. All test results were satisfactory. Refer to EMC and ES test reports in Section 17 Electromagnetic Compatibility and Electrical Safety of this submission document.

Performance testing - Acoustic power, beam profile, thermal evaluation, and focal length testing were performed according to design requirement specifications and verification and validation plan. All test results were satisfactory with no deviations from the applicable standards or protocols. Refer to summary of performance in Section 18 Performance Testing - Bench for more details.

VIII. SOFTWARE VERIFICATION AND VALIDATION TESTING

Software verification and validation testing was conducted and demonstrated as per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

IX. CLINICAL STUDY

The study was a single-center, a prospective, randomized, three-armed clinical study at UltraLaser Center, Monterrey, Mexico in compliance with international guidelines for Good Clinical Practices. An average fluence of 85 J/cm 2 was set as the initial treatment setting and the energy dose was increased or decreased in increments of 5 J/cm 2 according to the patient´s tolerance. A mean waist circumference reduction of 3.05 ± 5.95cm ($p<.0001$) from baseline was observed at 12 weeks follow up.

The subjects were evaluated initially, with follow-up after 4, 8 and 12 weeks. The adverse events reported were erythema, ecchymosis, and dysesthesia and were resolved during the course of the study without any treatment. There were no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) related to treatment with the investigational device. The mean pain score for the treated population was 7.35.

X. CONCLUSION

LIPOcel is substantially equivalent to the Predicate Device in terms of indications for use, handpiece size, aesthetic optimal temperature, patient contacting material, output waveform, maximum power output, and operating principle. Safety and performance testing was performed and Jeisys Medical Inc. has concluded that the device does not raise any significant questions of safety and efficacy and is substantially equivalent to the Predicate Device.