September 29, 2023

BeShape Technologies Ltd.
% Amit Goren
Regulatory Affairs Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
18 Hata'as Str., Suite 21
Kfar Saba, 4442518
Israel

Re: K231628
Trade/Device Name: BeShape One™ Device
Regulation Number: 21 CFR 878.4590
Regulation Name: Focused Ultrasound Stimulator System For Aesthetic Use
Regulatory Class: Class II
Product Code: OHV
Dated: September 11, 2023
Received: September 11, 2023

Dear Amit Goren:

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: 2023.09.29 09:50:00 -04'00'

Mark 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)*
K231628

Device Name
BeShape One™ Device

Indications for Use *(Describe)*
The BeShape One™ device delivers High Intensity, Non-Focused Ultrasound energy that can disrupt the Subcutaneous Adipose Tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. The BeShape One™ device 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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510(K) SUMMARY
BESHAPE ONE™ SYSTEM

510(k) Number K231628

Applicant Name:
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Date Prepared: September 11, 2023

Trade Name: BeShape One™

Classification Regulation:

Classification Name	Regulation No.	Product Code
Focused Ultrasound For Tissue Heat Or Mechanical Cellular Disruption	878.4590	OHV

Classification: Class II Medical Device

Predicate Device: The BeShape One device is substantially equivalent to the following FDA-cleared predicate device:

Manufacturer	Device	510(k) No.
Jeisys Medical Inc.	LIPOcel	K181896

Device Description:

The BeShape One™ device is a non-invasive, high intensity, non-focused US device intended for disruption of the subcutaneous adipose tissue and indicated for non-invasive waist circumference reduction. The BeShape One™ device utilizes continuous wave (CW) ultrasonic energy applied to the adipose tissue at a temperature of 47-49ºC. A cooling system maintains the skin temperature at below 35ºC. The device consists of hardware and software. These elements are integrated in the BeShape One™ console and applicator/hand piece. BeShape One™ is supplied as a console and two identical applicators. The device is portable and was specifically designed to be utilized in clinic environments.

The console is floor-standing and portable. It is controlled by a touch screen and consists of the following subsystems:

- Power Source
- Controller unit (CPU)
- Water cooling system (Chiller)
- Vacuum System
- Block Amplifier
- Touchscreen display monitor
- Personal computer and proprietary software
- Two designated applicator cradles
- Two designated applicator connector ports

The BeShape One™ device applicator is a mechanical handpiece with an internal rectangular bathtub-shaped chamber and consists of the following elements:

- Two parallel facing US transducers - Each transducer includes four piezoelectric (PZT) ceramic elements which convert electrical energy into acoustic energy in the ultrasound frequency range. Each transducer can transmit up to 1.5W/cm^2 of acoustic energy at a frequency of 2MHz.
- Vacuum - The vacuum provides effective fixation of the adipose tissue under the skin in the cup-shaped chamber of the Applicator.
- The cooling system which includes thermoelectric coolers (TEC) for ultrasound (US) transducers (TD) and a water-cooling system for the hot side of the thermoelectric coolers (TEC). The cooling system is intended to cool the applicator and skin to below 35°C.

The Applicator uses vacuum during the procedure, which draws adipose tissue under the skin into the inner cup-shaped chamber, thereby heating the subcutaneous adipose tissue.

Intended Use/Indication for Use:

The BeShape One™ device delivers High Intensity, Non-Focused Ultrasound energy that can disrupt the Subcutaneous Adipose Tissue (SAT) to provide a non-invasive

approach to achieve a desired aesthetic effect. The BeShape One™ device is specifically indicated for non-invasive waist circumference reduction.

Performance Standards:

The BeShape One™ device has been tested and complies with the following performance standards.

Standard Number	Standard Title
IEC 60601-1 Ed 3.2 2020-08	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 62304 Ed 1.1 2015-06	Medical device software - Software life cycle processes
IEC 60601-1-2 Ed 4.1 2020-09	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-62 Ed 1.0 2013-07	Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
ISO 10993-5 Ed 3 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Ed 3 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
IEC 14971 Ed 3 2019-12	Medical devices - Application of risk management to medical devices
IEC 60601-1-6 Ed 3.2 2020-07	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1 Ed 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices

The test report documents conclude that the BeShape One™ device complies with the requirements of all the above-mentioned standards. The test reports for the BeShape One™ device are provided in Sections 15 (Biological Evaluation), 16 (Software Validation), 17 (Electrical and EMD Safety Testing) and 18 (Ultrasound Safety Testing) of this 510(k) submission.

Non-Clinical (Bench) Performance Data:

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 and complied with the applicable standards and protocols. The acoustic output (ultrasound safety) testing is provided in Section 18 (Performance Testing – Bench) of this 510(k) submission.

Software validation testing in compliance with FDA guidelines for software validation and IEC 62304 standard requirements was also conducted. The software validation documents are provided in Section 16 (Software Validation) of this 510(k) submission.

Pre-Clinical (Animal) Performance Data:

The safety of the Beshape One™ Device for disruption of adipose tissue and non-invasive waist circumference reduction was demonstrated in a pre-clinical (animal) study. The pre-clinical, animal study demonstrated that the use of BeShape One™ device under the experimental conditions is safe, without being associated with any adverse effect. Furthermore, under the conditions of the study and in consideration of its intended clinical application, the BeShape One™ Device, intended for use for disruption of adipose tissue and indicated for use for non-invasive waist circumference reduction, passed all the pre-defined safety acceptance criteria for thermal safety, including temperature, lipid profile and micro and macro-histopathology requirements.

Clinical Performance Data:

The safety and efficacy of the Beshape One™ Device for disruption of adipose tissue and non-invasive waist circumference reduction was demonstrated in a prospective, single-arm, controlled study.

The study was a prospective, multi-center, single-arm study. Subjects received one treatment with the BeShape One™ device on the anterior abdomen. A total of four to six treatment areas were marked prior to treatment administration. Subsequently, two operating applicators (including the ultrasound transducers) were placed on two of the marked treatment areas and vacuum was activated, such that two treatment areas were treated simultaneously. The follow-up period included two visits at 6 weeks (6wk FU) and 12 weeks (12wk FU) post treatment. Subjects' waist circumference and abdominal fat thickness were measured and assessment were performed using the Clinical Global Aesthetic Improvement Scale (CGAIS) and subject self-rating GAIS and a 5 point Satisfaction Likert scale. The SAS comprised 72 participants.

The change from baseline to 12 weeks follow-up in waist circumference showed that there was a statistically significant decrease of -1.87 cm. (STD=2.62) in waist circumference. This difference was also clinically meaningful and met the performance goal of the study. The subject self-reported GAIS results showed that 55% of the subjects rated an improvement in their waist circumference reduction at 12 weeks post treatment. The investigator rated subject improvement using the CGAIS demonstrated that 72.3% of the subjects rated an improvement in their waist circumference reduction at 12 weeks post treatment. The subject satisfaction self-rating scale showed that 53.7% satisfaction at the 6 week visit follow up visit, with a decline at subsequent follow-up. The subjects rated a moderate level of comfort/pain. Abdominal fat thickness reduction at 12 weeks post treatment was -0.20 cm (STD=0.43). The most frequent Local Skin Reaction (LSR) were erythema and application site bruise. No abnormal vital signs (blood pressure, heart rate and temperature) were noted during the study.

In summary, the efficacy clinical data and safety results of the BeShape One™ clinical study presented above demonstrated the safety and effectiveness of the BeShape One™ Device for waist circumference reduction.

Substantial Equivalence:

The following table provides a comparison of the BeShape One™ device and the predicate LIPOcell device:

Characteristic	**Subject Device** **BeShape One** **(BeShape Technologies Ltd.)**	**Predicate Device** **LIPOcel** **(Jeisys Medical Inc., K181896)**
Device Classification, Indication for Use, Intended Use		
Device Classification	Class II	Class II
Classification Product Code	OHV	OHV
Regulation Number	878.4590	878.4590
Indications For Use	The BeShape One device delivers High Intensity, Non-Focused Ultrasound energy that can disrupt the Subcutaneous Adipose Tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. The BeShape One device is specifically indicated for non-invasive waist circumference reduction.	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.
Target Population	Adult subjects	Adult subjects
Anatomical Sites	Waist	Waist
Environment Used	In-office	In-office
Technological Characteristics		
Device Description	The BeShape One device delivers High Intensity, Non-Focused Ultrasound energy that can disrupt the Subcutaneous Adipose Tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. The BeShape One device is specifically indicated for non-invasive waist circumference reduction.	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.
Device Components	• Power source • Controller unit • Cooling system • Vacuum System • Touchscreen display monitor • PC and proprietary software • Applicator	• Power source • Controller unit • Cooling System -- • Touch LCD monitor • Software • Applicator

Characteristic	Subject Device BeShape One (BeShape Technologies Ltd.)	Predicate Device LIPOcel (Jeisys Medical Inc., K181896)
Operation Control	General Practitioner / Dermatologist	General Practitioner / Dermatologist
Mechanism for Heat Generation	High Intensity, Non-Focused Ultrasound	High Intensity, Focused Ultrasound
Power source	AC/DC power: 50-60 Hz 100-240VAC 5.5A	AC/DC power: 50-60 Hz 100-240VAC 5.5A
Energy Source	Piezoelectric ultrasonic transducer	Piezoelectric ultrasonic transducer
Frequency of US Energy	2 MHz	2 MHz
Cartridge Focal Length	Not Applicable	13 mm
Duration of Treatment	22 minutes of treatment	60 minutes of treatment
Treatment Temperature: **Skin Temperature:**	48°C 15 - 35°C	55°C 30 - 37°C
Temperature regulation	Temperature at the applicator is continuously monitored to ensure it does not exceed the maximum allowable temperature.	Temperature at the applicator is continuously monitored to ensure it does not exceed the maximum allowable temperature.
Cooling System	Water based	Water based
Rate of Heating (time to reach target temp)	5 minutes, at least	Not available
Treatment Area	40.5cm^3	30 x 30 (mm)
Dimensions	55.6cm(W)x60.8cm(D)x139.6cm(H)	43.8cm(W)x58cm(D)x108cm(H)
Weight	55 kg	80 kg
Sterilization	Non-sterile	Non-sterile
Single Use or Reusable	BeShape One device: reusable Applicators: reusable	LIPOcel device: reusable Applicators: reusable
Performance Testing		
Biocompatible patient-contacting materials (ISO 10993-1)	Yes, medical-grade materials	Yes, medical-grade materials
Thermal Safety	Bench testing verified thermal safety requirements	Bench testing verified thermal safety requirements
Software	Testing was performed to validate that the software met all requirements	Testing was performed to validate that the software met allrequirements
Electrical Safety per IEC 60601-1	Meets requirements	Meets requirements

Characteristic	Subject Device BeShape One (BeShape Technologies Ltd.)	Predicate Device LIPOcel (Jeisys Medical Inc., K181896)
Electromagnetic Compatibility (EMC) per IEC 60601-1-2	Meets requirements	Meets requirements

The BeShape One™ device has the same intended use as the LIPOcel device, including disruption of Subcutaneous Adipose Tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect and the same indication for use for non-invasive waist circumference reduction.

Furthermore, the technological characteristics of the BeShape One™ device and the predicate, LIPOcel device are similar, including similar device components (i.e., power source, control unit, water-based cooling system, operator interface and display monitor, software and applicator), similar mechanism of action (heating the tissue using ultrasound energy to achieve adipose tissue disruption and thus achieve waist circumference reduction), similar treatment administration, similar energy regulation methods, biocompatible materials, validation of software component, and similar compliance with electrical, EMC and high intensity ultrasound standards, as well as similar compliance with methods and standards to validate the safety of the Ultrasound energy. The most important technological characteristic, i.e., using US energy to deliver heat to the body area to induce the adipose tissue disruption for the treatment of non-invasive waist circumference reduction, is the same in both devices. As there are slight differences in the configuration of the ultrasound transducers and the type of ultrasound energy used in the BeShape One™ device, there are acceptable scientific methods to evaluate these aspects of the device, including compliance with FDA recognized methods and standards to demonstrate ultrasound safety and testing to validate the generated ultrasound energy output in the BeShape One ™ device is at least as safe and effective as the legally marketed, predicate LIPOcel device and meets the requirements of the standards. Addition, similar acceptable methods for demonstrating the safety and effectiveness of the device were employed, including pre-clinical (animal) and clinical testing. The gamut of performance testing provided in the 510(k) demonstrates the safety and effectiveness of the BeShape One ™ device and the substantial equivalence to the predicate device.

Conclusions:

Based on the performance testing provided in the 510(k) submission and comparison to the predicate device, the BeShape One™ device is substantially equivalent to the LIPOcel device (K181896) and may be legally marketed in the US.