

510(k) Summary

Applicant Information:

Company Name: CAO Group, Inc.
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Contact Person: Robert K. Larsen
Preparation Date: October 27, 2020

Device Name:

Trade Name: Ultimate Contour and Ultimate Contour Mini
Common Name 1: Massager, vacuum, radio frequency induced heat
Product Code 1: PBX
Regulation 1: 878.4400
Product Classification 1: Class II
Common Name 2: Focused ultrasound stimulator for aesthetic use
Product Code 2: OHV
Regulation 2: 878.4590
Product Classification 2: Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

Ultimate Contour, manufactured by CAO Group, Inc. (K171052)

UltraShape, manufactured by Syneron Medical, Ltd. (K141708)

Description of Submitted Device:

The Ultimate Contour is a medical device that combines the technologies of radio-frequency energy and ultrasound in one convenient unit. The Ultimate Contour utilizes a single power source and control circuitry that directs the emission of energy based on which operating screen is selected and which applicator handpiece is attached to the unit's delivery cable. Based on the attached handpiece, the Ultimate Contour delivers to the handpiece of the appropriate energy intensity based on the settings selected.

Delivered radio frequency energy is accomplished with the multi-nodal RF handpiece that contains RF energy to the treatment area and works to gently heat the tissue to induce collagen contraction and increase local circulation. The elevated temperature further works to provide temporary relief from pain and muscle spasms. The unit features an interactive color LCD touchscreen for adjusting device settings, as well as for viewing on-board tutorial videos.

Delivered ultrasound is accomplished with a piezo transducer located in the ultrasound handpiece that is bonded to the handpiece contact surface. The handpiece is applied directly to the patient skin at the abdominal area and the emitted ultrasound energy focuses within the subdermal fatty tissue, causing reduction in waist circumference.

The unit features an interactive color LCD touchscreen for adjusting device settings, as well as for viewing on-board tutorial videos.

The device is presented as two models. The first model (005-00035) is an integrated free-standing system. The second model (005-00036) is a portable, table-top style unit. Both units feature exactly the same internal electronics and components, the exact same software, the exact same attachments and accessories, and the exact same environment of use. The models differ only in the shape and dimensions of the mechanical enclosure of the control unit.

Indications for Use of the Submitted Device:

The submitted device is indicated for -

- 1) Application of non-thermal radio frequency for relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.
- 2) Application of ultrasound for non-invasive reduction in abdominal circumference on adults with a Body Mass Index (BMI) of 25 or greater.

Summary of Technological Characteristics and Substantial Equivalence:

	CAO Group, Inc. Ultimate Contour	CAO Group, Inc. Ultimate Contour K171052	Syneron Medical, Ltd. UltraShape K141708
Ultrasound Frequency	37kHz	Not Present	200kHz
Ultrasound Power	1.00 W/cm ²	Not Present	17 W/cm ²
Ultrasound Focal Distance	6mm	Not Present	15mm
Electrical Power Input (System)	100-240VAC, 50-60Hz, 207VA	100-240VAC, 50-60Hz, 207VA	110-120/200-240VAC, 50/60Hz
Cooling Method (Handpiece)	Heatsink/Air Convection	Heatsink/Air Convection	Not available
Cooling Method (Unit)	Heatsink / Fan air cooled	Heatsink / Fan air cooled	Not available
Application Time	10-40 minutes	10-40 minutes	30-60 minutes
Dimensions	(Model 005-00035): 19" x 19" x 50" (Model 005-00036): 13.75" x 14.5" x 14"	(Model 005-00035): 19" x 19" x 50" (Model 005-00036): 13.75" x 14.5" x 14"	25.6" x 38.6" x 78.75"
Weight	(Model 005-00035): 45.0 lbs. (Model 005-00036): 5.0 lbs	(Model 005-00035): 45.0 lbs. (Model 005-00036): 5.0 lbs	285.0 lbs.

	CAO Group, Inc. Ultimate Contour	CAO Group, Inc. Ultimate Contour K171052	Syneron Medical, Ltd. UltraShape K141708
User Interface	Interactive color LCD touchscreen	Interactive color LCD touchscreen	Interactive color LCD touchscreen
Patient- Contacting Materials	Stainless Steel Nylon Plastic	Stainless Steel Nylon Plastic	Stainless Steel ABS Plastic
Sterilization of Patient- Contacting Materials	None Specified	None Specified	None Specified
Environment of Use	Controlled medical office or practice	Controlled medical office or practice	Controlled medical office or practice
510(k) Number	Pending this application	K171052	K141708
Indications for Use	<ol style="list-style-type: none"> 1) Application of non-thermal radio frequency for relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite. 2) Application of ultrasound for non-invasive reduction in abdominal circumference on adults with a Body Mass Index (BMI) of 25 or greater. 	Application of non-thermal radio frequency for relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.	The UltraShape System delivers focused ultrasound energy that can disrupt subcutaneous adipose tissue (SAT) to provide a non-invasive approach to achieve a desired aesthetic effect. It is intended for non-invasive reduction in abdominal circumference.

Rationale for Substantial Equivalence:

The submitted device shares the same indications for use as the predicates. The submitted device utilizes the same energy type and means of energy application as the predicate devices. The submitted device is used by the same type of operator as the predicate devices. The submitted device provides for similar user interface and control mechanisms as the predicate devices. Ultrasound component of subject device has technological differences to compare to the predicate. Pre-clinical and clinical performance testing was performed to evaluate substantial equivalence of ultrasound component to the predicate.

Performance Data:
ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

The Ultimate Contour is demonstrated to comply with the performance requirements of IEC 60601-1: 3rd Edition, IEC 60601-1-2: 3rd Edition with gap analysis to 4th Edition, and IEC 60601-1-6.

PERFORMANCE BENCH TESTING

Bench testing per internal verification testing demonstrates that the Ultimate Contour meets the essential performance requirements established for the device, including measurements of the radio frequency power

generated, and essential aspects of hardware and software performance. The software of this device is stated as a Major level of concern since failure of the software could present significant risk to the patient. All essential functions are demonstrated to work according to design specifications.

BIOCOMPATIBILITY

Materials used in the patient-contacting portions of this device are equivalent to legally marketed reference devices listed above that incorporate patient-contacting articles used for contacting similar tissues.

CLINICAL PERFORMANCE TESTING

A clinical evaluation of the device on a representation of the intended population was performed in a single-site single-arm study. The study evaluated the safety and effectiveness of the device in waist circumference reduction. A total of 42 subjects completed the treatment regimen of 3 applications of the device with one week between each treatment, and 1-week and 4-week follow ups. The safety analysis included all subjects who participated at any point during the course of the study. Effectiveness was gauged by determining if waist circumference reduction was achieved relative to a value identified as clinically meaningful, a value of at least 1 inch of waist circumference reduction at the conclusion of the treatment regimen. The clinically meaningful value was identified based on published studies utilizing other devices for the same purpose. Measurements were conducted prior to and after each treatment, and at the 1-week and 4-week follow-up visits. Clinicians were blinded relative to measuring pre-treatment and post-treatment.

The study included subjects age 18 or older who met all inclusion criteria and none of the exclusion criteria. The majority of study subjects were Caucasian females. Mean age of the subjects was 42.8 years. Mean baseline waist circumference prior to the first treatment was measured at 40.95 inches, and an average initial BMI of 29.36. The primary effectiveness endpoint measured the difference between waist circumference prior to the first treatment with the device. The safety endpoint assessed all adverse events and serious adverse events occurring during the study.

The study results for the primary endpoint demonstrated an average circumference reduction of 2.0 inches to the 4-week follow up visit, which was statistically significant compared to the target threshold of 1.0 inches ($p=0.05$). The greatest circumference reduction for this period was measured at 3.75 inches, and the least circumference reduction was measured at 0.75 inches. T-test and Kolmogorov-Smirnov tests demonstrated that the data can be considered normally distributed. Correlation analysis comparing the baseline measurements and 4-week follow-up measurements returned a correlation score of 0.9901. With all missing data imputed with a least-favorable regimen outcome (0.75 inch reduction), the effect of device treatment on circumference reduction remained greater than the 1.0 inch reduction threshold. The treatment was administered without anesthetic. 7 subjects reported a sensation of ringing or buzzing in the ears, which was substantial enough to cause 2 of the subjects to discontinue participation. Follow-up audiology assessment with these subjects identified no substantial or worsening audible capabilities. Most adverse events resolved within 1-2 days after the treatment. These included skin rash, changes in bowel movement, and changes in urine consistency. The events were either self-resolving or resolved with the use of over-the-counter products.

Conclusion:

Comparison of subject and predicate devices identified technological similarities and differences. Performance testing was performed to evaluate substantial equivalence of dissimilar technological characteristics. Based on technological comparison to predicate devices and the results of pre-clinical and clinical performance testing, the Ultimate Contour device is substantially equivalent to the identified predicate devices.