October 28, 2020

CAO Group, Inc.
Robert K. Larsen
Regulatory Affairs Manager
4628 West Skyhawk Drive
West Jordan, Utah 84084

Re: K201475
Trade/Device Name: Ultimate Contour, Ultimate Contour Mini
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: PBX, OHV
Dated: July 7, 2020
Received: July 13, 2020

Dear Robert K. Larsen:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201475

Device Name
Ultimate Contour, Ultimate Contour Mini

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Applicant Information:

Company Name: CAO Group, Inc.
Company Address: 4628 West Skyhawk Drive
West Jordan, Utah 84084 U.S.A.
Company Phone: 1-801-256-9282
Company Fax: 1-801-256-9287

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	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.