October 20, 2017

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

Re: K171052
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
Dated: September 14, 2017
Received: September 18, 2017

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171052

Device Name
Ultimate Contour
Ultimate Contour Mini

Indications for Use *(Describe)*
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.

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

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 17, 2017

Device Name:

Trade Name:	Ultimate Contour
Common Name:	Massager, vacuum, radio frequency induced heat
Product Code:	PBX
Regulation:	878.4400
Product Classification:	Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

Venus Legacy, manufactured by Venus Concept, Ltd. (K143554)

Legally Marketed Reference Devices:

Axiem Touch-N-Go Registration Pointer, manufactured by Medtronic Navigation, Inc. (K141833)

Bi-Funnel Gastrostomy Feeding Tube with ENFit Connector, manufactured by Xeridiem Medical Devices (K171347)

Description of Submitted Device:

The Ultimate Contour is a body sculpting device that combines the technologies of radio-frequency energy 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 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.

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 -
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.

Summary of Technological Characteristics and Substantial Equivalence:

	CAO Group, Inc. Ultimate Contour	**Venus Concept, Ltd. Venus Legacy**
Radio Frequency	1MHz	1MHz
Radio Power (Max.)	80W	150W
Electrical Power Input (System)	100-240VAC, 50-60Hz, 207VA	100/110/240VAC, 50/60Hz, 670VA
Cooling Method (Handpiece)	Heatsink/Air Convection	Not available
Cooling Method (Unit)	Heatsink / Fan air cooled	Not available
Application Time	10-40 minutes	30 minutes
Dimensions	(Model 005-00035): 19" x 19" x 50" (Model 005-00036): 13.75" x 14.5" x 14"	15.75" x 15.75" x 40"
Weight	(Model 005-00035): 45.0 lbs. (Model 005-00036): 5.0 lbs	88.0 lbs.
User Interface	Interactive color LCD touchscreen	Interactive color LCD touchscreen
Patient-Contacting Materials	Stainless Steel Nylon Plastic	Stainless Steel ABS Plastic
Sterilization of Patient-Contacting Materials	None Specified	None Specified
Environment of Use	Controlled medical office or practice	Controlled medical office or practice
510(k) Number	K171052	K143554
Indications for Use	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 Venus Legacy CX device is intended for the treatment of the following medical conditions; using LB2 and LF2 applicators for the delivery of non-thermal RF combined with massage and magnetic field pulses: • Relief of minor muscle aches and pain, relief of muscle spasm • Temporary improvement of local blood

	CAO Group, Inc. Ultimate Contour	Venus Concept, Ltd. Venus Legacy
		circulation • Temporary reduction in the appearance of cellulite

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.

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, 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
Clinical performance testing for radio frequency performance was conducted via a single-site study on 5 human patients with varying skin pigmentation and demonstrates that the device is capable of heating skin tissues of the abdomen, thigh, arm, neck, and face to 40-45°C within 10 minutes without exceeding 45°C, in support of the claimed indication for this device.

Conclusion:

The Ultimate Contour is substantially equivalent to the listed predicate. This device shares identical intended use, identical operating principles, similar design features, and similar functional and performance characteristics.