DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 31, 2015

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

Re: K150585
Trade/Device Name: Ascent 3D
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: II
Product Code: EBZ
Dated: November 19, 2015
Received: November 23, 2015

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 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" (21CFR 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 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 yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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)*
K150585

Device Name
Ascent 3D

Indications for Use *(Describe)*
For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light.

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

Prepared By: Robert K. Larsen
Preparation Date: December 21, 2015

Device Name:

Trade Name:	Ascent 3D
Common Name:	Dental Curing Light
Product Code:	EBZ
Regulation:	872.6070
Product Classification:	Ultraviolet Activator for Polymerization Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

Palmlight 10, manufactured by CAO Group, Inc. (K061341)

Rationale for Substantial Equivalence:

The submitted device and identified predicate device share exactly identical indications for use: For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light. The submitted device and predicate device share similar design features including emission sources, operating controls, key constructional components, and materials of construction. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output, emission wavelngth, and energy type.

Description of Submitted Device:

The Ascent 3D is a polymerization light source device for delivering light energy to polymerizable dental materials applied to human teeth in conjunction with a variety of procedures and treatments. This energy is generated by solid-state light-emitting diodes (LEDs), which provide a consistent and reliable generation of light energy at 390-520nm with an average optical output of 1600 milliwatts. The LEDs are positioned at the terminal end of the device, allowing for direct illumination of the treatment site without the use of light pipes or other optically conductive appendages. The device features three LEDs that are spatially positioned to illuminate three surfaces or planes of the tooth simultaneously. The device controls allow the operator to select which combination of LEDs are active and the emission time. Emission is initiated by pressing a button, and can be interrupted by pressing the same button or by allowing the selected emission time to expire. The device is constructed of a biocompatible plastic such as ABS, and coated aluminum. The device is powered from an internal rechargeable battery that is charged from an external power supply when not in use.

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Indications for Use of the Submitted Device:

The submitted device is indicated for use -
For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light.

Technological Characteristics and Substantial Equivalence:

	CAO Group, Inc. Ascent 3D	**CAO Group, Inc. PalmLight 10**
Wavelength	390-520nm	377-490nm
Optical Output Intensity	1-LED: 550mW 2-LEDs: 1000mW 3-LEDs: 1550mW	Standard: 1100mW Boost: 1425mW
Optical Output Fluence	> 750 mW/cm^2 per LED	Standard: 2200 mW/cm^2 Boost: 2850 mW/cm^2
Cooling System	Passive heatsink	Passive heatsink
Emission Patterns	Left, Center, Right, Left-Center, Center-Right, Left-Right, Left-Center-Right	Continuous, Pulse (0.25s pulse width, 4Hz), Ramp (0 to standard intensity within first 5 seconds), Boost (approximately 120% of standard)
Light Source	LED	LED
Cycle Times	3, 5, or 10 seconds	5, 10, 15, or 20 seconds
Battery Specifications	7.4VDC, 1400mAh	7.4VDC, 1400mAh
Input Power Requirements	12VDC, 1.7A	12VDC, 1.7A
Power Supply Specifications	100-240 VAC @ 50-60Hz, 0.6A	100-240 VAC @ 50-60Hz, 0.6A
Enclosure Materials of Construction - Handpiece - Probe - Lens Cover	 Cast aluminum ABS (acrylonitrile-butadiene-styrene) PC (polycarbonate)	 Cast aluminum ABS (acrylonitrile-butadiene-styrene) PC (polycarbonate)
Dimensions - Handpiece - Probe	 16.5cm L x 2.6cm W x 3.5cm D (6.5 x 1.0 x 1.3 inches) 10.5cm L x 2.9cm W x 3.4cm D (4.1 x 1.1 x 1.3 inches)	 16.5cm L x 2.6cm W x 3.5cm D (6.5 x 1.0 x 1.3 inches) 10.2cm L x 1.9cm W x 1.9cm D (6.5 x 1.0 x 1.3 inches)
Weight	7 ounces (200 grams)	7.8 ounces (220 grams)
510(k) Number	K150585	K061341
Indications for Use	For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light.	For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light.

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Conformity to Standards:

The Ascent 3D is designed to comply with the performance requirements of IEC 60601-1: 3rd Edition, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-2-57.

Performance Data:

Bench testing on an evaluation sample of the submitted was performed consistent with internal requirements:

- **Ascent 3D Depth of Cure Analysis**
  This test was conducted according to the following standard:
  ISO 4049:2009 - Dentistry – Polymerbased restorative materials
  Comparative testing to Palmlight 10 (K061341) was also conducted

- **QAC-I03481 - Final process inspection of Ascent 3D Probe**
- **QAC-I03482 - Final process inspection of Ascent 3D Handpiece**
- **Ascent 3D Sensor Verification Test**
- **Ascent 3D Main and Safety Specification Verification Test**

These tests were conducted according to the following standards:

IEC 60601-1:2005 3rd Edition - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 4th Edition - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard Electromagnetic compatibility – Requirements and tests

IEC 60601-1-6:2013 Edition 3.1 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 60601-2-57:2011 1st Edition - Medical electrical equipment – Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

IEC 62304:2006 1st Edition - Medical device software – Software life cycle processes

Conclusion:

The Ascent 3D is substantially equivalent to the listed predicate. This device shares identical intended uses, identical operating principles, similar design features, and similar functional and performance characteristics.