K061341

510(k) Summary of Safety and Effectiveness

CAO Group, Inc.
86863 South 700 West
Sandy, UT 84070
Tel: 801-256-9282 Fax: 801-256-9287

JUN 12 2006

Robert Larsen,
Preparation Date: April 25, 2006

Device Name:

Trade Name:	Palmlight 10
Common Name:	LED Dental Curing Light
Product Classification:	Activator, Ultraviolet, For Polymerization (872.6070)

Legally Marketed Predicate Devices for Substantial Equivalence:

Bluephase 16i

Palmlight (CAO Group, Inc.)

Palmlight (Ultradent Products, Inc.)

Rationale for Substantial Equivalence:

The aforementioned curing light devices share similar indications for use in the oral environment, similar design features including wavelength, output power, and light source. The devices share similar applications with regards to applying light energy to dental materials for the purpose of polymerizing or otherwise energizing said materials.

Description of Submitted Device:

The Palmlight 10 is a dental curing light source that employs high power light emitting diodes (LED's) to generate light in the wavelengths between 390 and 500nm. This wavelength of light is readily absorbed by photoinitiators in a variety of dental compositions. Such initiators begin a polymerization reaction that causes these dental compositions to harden. The device features an internal rechargeable battery, allowing the device to be used in a cordless fashion. The device can be placed in a charging cradle when not in use, or can be attached to a power supply such that the device can be used or charged while attached to the power supply. The device features the ability to select from preset time increments for activating the device. The user can also select from 4 different

output modes. The device features and on/off button to activate and deactivate the LED's. The device features a power down program such that the unit's display is deactivated if the unit is dormant for an extended period of time. The charging cradle features a power output display to assist the end user in determining the performance of the device.

Intended Uses of the PalmLight 10 curing light system:

The device is intended to be used on a variety of dental compositions within the oral cavity. See Indications for Use on page 2-1.

Technological Characteristics and Substantial Equivalence:

The Bluephase 16i uses LED's to generate light energy in the 430-490nm range with a power output of 1600mw/cm^2. This system features a removable battery back system, allowing the device to be used in a cordless configuration. The system also incorporates a power adaptor, allowing the unit to be attached to power supply and used in this condition. The device is indicated for curing dental compositions such as composites and luting cements. The system features a charging base with a built in power indicator. The system allows the user to select from preset modes and activation times.

The Palmlight, manufactured by CAO Group, Inc. uses LED's to generate light energy in the 400-460nm range with a power output of a minimum 800mW/cm^2. The system features a light, compact design with a permanent attachment to the power supply. The device is indicated for curing dental compositions such as composites, luting cements, and sealants. The system allows the user to select from preset modes and activation times.

The Palmlight, manufactured by Ultradent Products, Inc. uses LED's to generate light energy in the 400-460nm range with a power output of a minimum 800mW/cm^2. The system features a light, compact design with a permanent attachment to the power supply. The device is indicated for curing dental compositions such as composites, luting cements, and sealants. The system allows the user to select from preset modes and activation times.

Performance Standards:

The Palmlight 10 dental curing light complies with the safety and performance requirements of IEC 60601-1:1998+A1, IEC 60601-1-2:2004 and IEC 60825-1:1993+A1+A2.

Clinical Performance Data

See Part 7: Performance Data

Conclusion

The Palmlight 10 is substantially equivalent to the listed dental curing light devices without raising any issues of safety or effectiveness. This device shares similar intended uses, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2006

Mr. Robert K. Larsen
Operations Director
CAO Group, Incorporated
8683 South 700 West
Sandy, Utah 84070

Re: K061341
Trade/Device Name: Palmlight 10
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: April 25, 2006
Received: May 15, 2006

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.

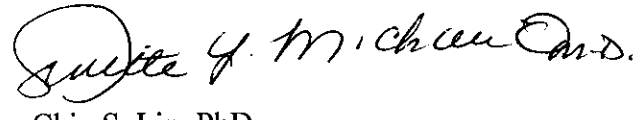
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061341

Device Name: *Palmlight 10*

Indications For Use:

For light activated polymerization of dental materials such as composites, luting cements, adhesives, and sealants using visible and near-UV light.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...Number: K061341

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)