K020057

AUG 2 7 2002

CAO GROUP

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Tracy S. Best, Consultant for Regulatory Affairs

Preparation Date: January 03, 2002

Summary of Safety and Effectiveness for the:

Trade Name: Palmlight 410-490 nm

Common Name: Dental curing light

Classification Name: Activator, Ultraviolet, for Polymerization

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Legally Marketed Predicate Devices for Substantial Equivalence:

* Ultradent Palmlight, Distributed by Ultradent Products, Inc.

* Jetlite 4000, Manufactured by J. Morita USA, Inc.

Rationale for SE: The aforementioned devices and the accompanying delivery mechanisms share similar indications for use in oral application, similar design features including; light spectrum, and beam integrity. Control systems such as interlock devices, (safety systems) are constantly monitored for user intervention. Functional features such as delivery power and energy type are also similar to the aforementioned devices.

Description of Submitted Device:

The Palmlight is a corded or cordless (battery operated) hand-held device. No filters are required to block out unnecessary rays. The light created by these diodes are specifically optimum for curing (430 to 500 nm). The Palmlight LED System is an instrument for use in the application of restorative compounds, sealants, and whitening compounds. The light is produced by a high intensity light emitting diode. With an adjustable light output of up to 500 Milliwatts. Therefore the applied for indications of use are warranted. Delivery devices (replacement tips) for the hand held probe are part of the package that allows the user to use the device with or without using direct current as rechargeable batteries are part of the handle. .

Intended Uses of the Elite Family Lasers:

A dental device intended to polymerize dental pit and fissure sealants or restorative materials by transmission of light via a light emitting diode.

Technological Characteristics and Substantial Equivalence:

The Ultradent Palmlight is identical in features and light output. The variable light output and the ability to use the device with or without power cord (rechargeable batteries) is the same as the submitted device. Both the submitted device and this predicate device are used in the curing of composites that are photo-activated including restorative and whitening materials.

The Jetlite 4000 uses similar transmission of light technology with similar light output by a blue Light Emitting Diode (LED). The indications for use are the same. This and the submitted device are used in dentistry for the photo-activation and curing of dental composites.

Performance Standards

The Palmlight complies with the requirements of 21 CFR Sub Chapter J, as required by 21 CFR 1010.2

Clinical Performance Data

None included with this submission.

Conclusion:

The Palmlight System is substantially equivalent to other existing oral systems in commercial distribution. The Palmlight is designed to meet the electrical safety requirements of IEC 601-1. The high intensity light emitting diode is operated by logic circuitry. Therefore, we believe that the Palmlight is substantially equivalent to its predicate devices cited above without raising any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2002

Ms. Tracey S. Best
Regulatory Consultant
CAO Group, Incorporated
8685 South 7th West
Sandy, Utah 84070

Re: K020057
Trade/Device Name: Palmlight
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: May 30, 2002
Received: June 4, 2002

Dear Ms. Best:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020057

Device Name: Palmlight

Indications For Use:

Oral Applications:

A source of illumination for curing photo-activated dental restorative materials, adhesives, pit and fissure sealants and activating tooth whitening materials via a light emitting diode (LED).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K020057

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