JUN 2 4 2004

510(k) SUMMARY

K041372

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872

CONTACT: P. Jeffery Lehn

DATE PREPARED:

TRADE OR PROPRIETARY NAME: SmartLite™ PS Pen-Style LED Curing Light

CLASSIFICATION NAME: Ultraviolet Activator for Polymerization (872.6070)

PREDICATE DEVICES:

SmartLite™ iQ LED Curing Light	K031615
Spectrum™ 800 Curing Unit	K982318

DEVICE DESCRIPTION:

The SmartLite™ PS Pen-Style LED Curing Light is a cordless, battery-powered unit designed for curing VLC materials whose initiator systems are sensitive to light in the 450-475 nm wavelength region of the visible spectrum. The unit is based ion LED (light emitting diode) technology for light generation.

The SmartLite™ PS Pen-Style LED Curing Light includes:

- A handpiece with control electronics and an inductively-recharged battery
- A probe with a single LED at the tip
- A base/recharger unit that plugs directly into main power
- An optional eye shield

INTENDED USE:

The SmartLite™ PS Pen-Style LED Curing Light is indicated for curing camphorquinone-based visible light cured (VLC) dental materials.

TECHNOLOGICAL CHARACTERISTICS:

The SmartLite™ PS Pen-Style LED Curing Light is substantially equivalent to K031615 in intended use, operation, wavelength range, and light source.

The SmartLite™ PS Pen-Style LED Curing Light is substantially equivalent to K982318 in intended use, operation.

We believe the similarity of the SmartLite™ PS Pen-Style LED Curing Light to the legally marketed predicate devices and the performance data provided support the safety and effectiveness of the SmartLite™ PS Pen-Style LED Curing Light for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2004

Mr. P. Jeffery Lehn
Director, Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17405-0872

Re: K041372
Trade/Device Name: SmartLite™ PS Pen-Style LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: May 19, 2004
Received: May 24, 2004

Dear Mr. Lehn:

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.

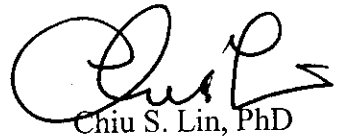
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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) you may obtain. 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,



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 STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K041372

Device Name: **SmartLite™ PS Pen-Style LED Curing Light**

Indications for Use:

The SmartLite™ PS Pen-Style LED Curing Light is indicated for curing camphorquinone-based visible light cured (VLC) dental materials

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

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

510(k) Number: K041372