SEP 15 1998

DENTSPLY

510(k) SUMMARY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
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P. J. Lehn Telefax (717) 849-4343

K982318

CONTACT: P. Jeffery Lehn

DATE PREPARED: June 29, 1998

TRADE OR PROPRIETARY NAME: SPECTRUM™ 800 CURING UNIT

CLASSIFICATION NAME: Unclassified

COMMON OR USUAL NAME: Visible light activator for polymerization

PREDICATE DEVICES: Spectrum™ Curing Light K951425

DEVICE DESCRIPTION: The SPECTRUM™ 800 CURING UNIT is a visible light emitting photopolymerization unit that produces light used to photoactivate dental resin products.

INTENDED USE: The SPECTRUM™ 800 CURING UNIT provides visible light irradiation for the curing of dental VLC resin products.

TECHNOLOGICAL CHARACTERISTICS: The SPECTRUM™ 800 CURING UNIT is identical to the Spectrum™ Curing Light (K951425) except for cosmetic changes to the appearance and operating features and an increased wattage light bulb. The same filter used for the Spectrum™ Curing Light is used for the SPECTRUM™ 800 CURING UNIT and controls the wavelength of light that is emitted by the unit. Both curing units feature a radiometer built into the base. However, the SPECTRUM™ 800 CURING UNIT radiometer is a digital type, whereas the Spectrum™ Curing Light radiometer is a red light/green light type.

An additional difference in the SPECTRUM™ 800 CURING UNIT from the Spectrum™ Curing Light is the intensity adjustment feature of the light. The operator can dial the intensity of the light. This feature will ensure the operator quality repeat output performance every time the light is used. This feature also allows the operator the ability to match the restoration type with the intensity required.

We believe that the similarity of the SPECTRUM™ 800 CURING UNIT to the predicate device and the performance and safety data provided support the safety and effectiveness of the SPECTRUM™ 800 CURING UNIT for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1998

Mr. P. Jeffrey Lehn
Director, Corporate Compliance
and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K982318
Trade Name: Spectrum 800 Curing Unit
Regulatory Class: II
Product Code: EBF
Dated: June 29, 1998
Received: July 2, 1998

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: _____

Device Name: SPECTRUM™ 800 CURING UNIT

The SPECTRUM™ 800 CURING UNIT provides visible light irradiation for the curing of dental VLC resin products.

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982318