K043530

JAN 2 5 2005

510(k) Summary
for
Designs for Vision Inc.
Curing Light

1. SPONSOR

Designs for Vision, Inc.
760 Koehler Avenue
Ronkonkoma, NY 11779

Contact Person: Richard Feinbloom
Telephone: 631-585-3300

Date Prepared: December 20, 2004

2. Device Name

Proprietary Name: DVI Curing Light
Common/Usual Name: dental curing light
Classification Name: ultraviolet activator for polymerization

3. PREDICATE DEVICES

Dentsply SmartLite (IQ) LED Curing Light (K041372)

Sybron Dental L.E. Demetron (K021797).

4. DEVICE DESCRIPTION

The DVI Curing Light consists of three major components; a handpiece, curved fiber optic end tip, and cradle. The handpiece contains the LED light source and a fiber optic light guide that directs light to the treatment area on the patient. The handpiece is placed in a cradle, which is connected via a plug-in transformer to an AC outlet for charging. A Protective light-shield and Fiber-optic end-tips are accessories provided with the DVI Curing Light, which support the operation and maintenance of the device.

The DVI curing light initiates curing (polymerization) of materials that are activated by photo initiators with an absorption in the wavelength range of

between 405 to 470 nm. It is recommended that materials manufacturer's directions be followed for curing times. It is recommended that curing times be extended when curing through the tooth structure or when the distance from the curing light end tip to the material exceeds 3 mm.

5. INTENDED USE

The DVI Curing Light is a dental curing light that is intended for the photopolymerization of dental resins.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed and predicate devices consist of a handpiece with a fiberoptic tip. The handpiece of the proposed DVI Curing Light and the predicate devices sit in a cradle. The handpiece is removed from the cradle during operation. The cradles of both the proposed and predicate devices serve as a charging base for the handpieces.

The operational principles of the proposed and predicate devices are identical in that they are LED devices used for photopolymerization of dental resins. The tip of the handpiece is oriented appropriately relative to the material being photopolymerized and the selected treatment time is initiated. In all devices, the light source is an LED light source located in the handpiece.

7. PERFORMANCE TESTING

The following testing was conducted to evaluate the functional performance and safety of the proposed DVI Curing Light:

- Software and hardware verification and validation
- Electrical safety and electromagnetic compatibility
- Resin polymerization times

The test results confirm that the proposed DVI Curing Light is safe and effective for use as a curing light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2005

Designs for Vision, Incorporated
C/O Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K043530
Trade/Device Name: DVI Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: December 20, 2004
Received: December 21, 2004

Dear Ms. McNamara-Cullinane:

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.

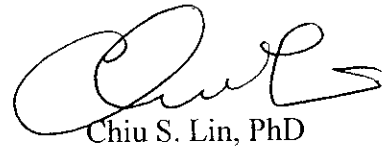
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K043530

Device Name: DVI Curing Light

Indications for Use:

The DVI Curing Light is a dental curing light that is intended for photopolymerization of dental resins.

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)

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

510(k) Number: K043530