JUN 23 2006

K061395

ADDENT

510(k) SUMMARY

Submitters Name: Joshua Friedman, D.D.S

Address: AdDent, Inc
43 Miry Brook Rd.
Danbury, CT 06810

Phone: (203) 778-0200

Fax: (203) 792-2275

Device Name: Calset Composite Heater

Common Name: Composite Warmer

Classification Name: Not officially classified

Marketed Device of Equivalence: Aesthetic Warmer. Product code EFC, regulation number 872.6100 (exempt).

Description of the Device:

The Calset is a warming device used to heat dental materials prior to their use in the mouth. It consists of a base unit that contains a heating element a temperature control circuit with LED indicators, a removable metal tray that is designed to hold different materials and a low voltage wall transformer that provides power to the unit.

Intended Use: The Calset unit is used to warm dental composite materials to130°F (54°C) or 155°F (68°C). It is also used to warm anesthetic carpules to 98°F (37°C) (body temperature).

Characteristics of the Calset Compared to Predicate Device: Both the Calset and the Anesthetic Warmer heat material that are in contact with the patient. The SE device heats anesthetic solution to body temperature (98°F). The Calset has three temperature settings 98°F (37°C), 130°F (54°C) or 155°F (68°C). The 98°F setting on the Calset is used together with a removable metal tray that holds anesthetic carpules.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

Joshua Friedman, DDS
President
AdDent, Incorporated
43 Miry Brook Road
Danbury, Connecticut 06810

Re: K061395
Trade/Device Name: Calset Composite Heater
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Codes: EBZ, EFC, and EEG
Dated: May 17, 2006
Received: May 24, 2006

Dear Dr. Friedman:

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): K061395

Device Name: Calset Composite Heater

Indications for Use:

Intended Use: The Calset unit is used to warm dental composite materials and whitening bleach to130°F (54°C) or 155°F (68°C). It is also used to warm anesthetic carpules to 98°F (37°C) (body temperature).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

...on Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...Number: K061395