K081810

EXHIBIT 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk
80 Oakland Street
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Watertown, MA 02472 USA

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DEVICE:
Trade Name: *Pulpdent Temporary Crown and Bridge Material*
Classification Name: Temporary Crown and Bridge Resin
Class: II
FDA Product Code: 76 EBG, 21 CFR Part 872.3770

PREDICATE DEVICES:

Luxatemp, DMG

Luxatemp Solar, DMG

Sci-Span, Scientific Pharmaceuticals Inc.

Integrity, Dentsply International

CosmeTemp, Cosmedent Inc.

DESCRIPTION AND INTENDED USE:

Pulpdent Temporary Crown and Bridge Material is a dual-cure, glass-filled, resin composite used by the dental professional to make a temporary prosthesis, such as a crown or bridge, to be used until a permanent restoration can be fabricated.

COMPARISON WITH PREDICATE PRODUCTS:

Pulpdent Temporary Crown and Bridge Material is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3770.

SAFETY AND EFFECTIVENESS:

Pulpdent Temporary Crown and Bridge Material is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above that have been on the market and used by dental professionals for more than 15 years with no serious safety or effectiveness problems. *Pulpdent Temporary Crown and Bridge Material* is fabricated from materials that have been used in the dental industry for many years.

According to the NIH Technology Assessment Conference on *Effects and Side-Effects of Dental Restorative Materials*: "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the United States."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
P.O. Box 780
Watertown, Massachusetts 02472

Re: K081810
Trade/Device Name: Pulpdent Temporary Crown and Bridge Material
Regulation Number: 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: June 18, 2008
Received: June 26, 2008

Dear Mr. Berk:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081810

INDICATIONS FOR USE

510 (k) Number *(if known)*

Device Name: ***PULPDENT TEMPORARY CROWN AND BRIDGE MATERIAL***

Indications for Use:

Pulpdent Temporary Crown and Bridge Material is used by the dental professional to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.

Prescription Use X 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

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