

K071278

EXHIBIT 2

SUMMARY OF SAFETY AND EFFECTIVENESS DATA JUN 29 2007

Kenneth J. Berk
80 Oakland Street
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DEVICE:

Trade Name: PULPDENT EMBRACE™ DUAL CURE COMPOSITE MATERIALS

Classification Name: Tooth shade resin material

FDA Product Code: 76 EBF, 21 CFR Part 872.3690

PREDICATE DEVICES:

Pulpdent Embrace™ Resin Cement
Pulpdent Embrace™ WetBond Pit and Fissure Sealant
Pulpdent ResiLute Resin Cement
Pulpdent VLC Resin Cement
Pulpdent Embrace™ WetBond Restorative Materials
Apex Dental Materials anchor®
Den-Mat Core Paste XP

DESCRIPTION AND INTENDED USE:

Embrace™ Dual Cure Composite Materials are multi-purpose, hydrophilic, fluoride-releasing, resin-based materials that contain no Bisphenol A and bond tightly to dentition.

Embrace™ Dual Cure Composite Materials are used to permanently cement dental posts, porcelain crowns, inlays, onlays, bridges, porcelain/laminate veneers and periodontal splints, to repair porcelain crowns intra-orally and as a build-up and repair material.

COMPARISON WITH PREDICATE PRODUCTS:

PULPDENT DUAL CURE COMPOSITE MATERIALS are substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

SAFETY AND EFFECTIVENESS:

PULPDENT DUAL CURE COMPOSITE MATERIALS are 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 872.3690, 872.3275 and 872.3765.

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

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

JUN 29 2007

Re: K071278

Trade/Device Name: Embrace™ Dual Cure Composite Materials
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF and EMA
Dated: May 02, 2007
Received: May 07, 2007

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.

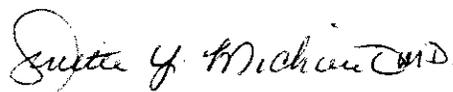
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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) K071278

Device Name PULPDENT EMBRACE™ DUAL CURE COMPOSITE MATERIALS

Indications for Use:

Embrace™ Dual Cure Composite Materials are multi-purpose, hydrophilic, fluoride-releasing, resin-based materials that contain no Bisphenol A and bond tightly to dentition.

Embrace™ Dual Cure Composite Materials are used to permanently cement dental posts, porcelain crowns, inlays, onlays, bridges, porcelain/laminate veneers and periodontal splints, to repair porcelain crowns intra-orally and as a build-up and repair material.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

or

Over-The-Counter Use _____
(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 Runne

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

510(k) Number: 628107 K071278