DEC 1 0 2003

K032953

EXHIBIT 2

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk
80 Oakland Street
PO Box 780
Watertown, MA 02472 USA

Telephone: 617-926-6666
Fax: 617-926-6262
Email: Pulpdent@pulpdent.com

DEVICE NAME: ***Embrace™ WetBond™ Restoration & PFM Repair Kit***

PREDICATE DEVICES:
Kuraray Clearfil Porcelain Repair Kit
Ultradent Porcelain Repair Kit
Ivoclar Vivadent Ceramic Repair Kit

Components of the Embrace™ WetBond™ Restoration & PFM Kit
- Pulpdent Embrace First Coat
- Pulpdent Embrace Seal-n-Shine
- Pulpdent Embrace Opaquer
- Pulpdent Kool-Dam
- Pulpdent Porcelain Etch Gel

DESCRIPTION AND INTENDED USE:
Embrace™ WetBond™ Restoration & PFM Repair Kit is a convenience kit used by the dentist to repair restorations. The components were designed for bonding to all restorative, metal and ceramic surfaces. The kit provides materials for preparing, priming, opaquing and protecting surfaces, and for sealing, finishing and polishing the final repair or restoration.

COMPARISON WITH PREDICATE PRODUCTS:
Embrace™ WetBond™ Restoration & PFM Repair Kit is substantially equivalent in design, composition and intended use to the kits listed above. The component materials in *Embrace™ WetBond™ Restoration & PFM Repair Kit* have been found to be substantially equivalent under the 510(k) premarket notification process. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS:
Embrace™ WetBond™ Restoration & PFM Repair Kit 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 872.3200.

The chemical ingredients used in *Embrace™ WetBond™ Restoration & PFM Repair Kit* are used in the predicate products and in other established dental materials. Though there is no ISO or ANSI/ADA standard applicable to *Embrace™ WetBond™ Restoration & PFM Repair Kit*, laboratory testing has shown that *Embrace™ WetBond™ Restoration & PFM Repair Kit* is equivalent in physical and mechanical properties to the predicate products.

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. 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

DEC 1 0 2003

Mr. Kenneth J. Berk
Director,
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

Re: K032953
Trade/Device Name: Embrace™ WetBond ™ Restoration & PFM Repair Kit
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: September 10, 2003
Received: September 22, 2003

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.

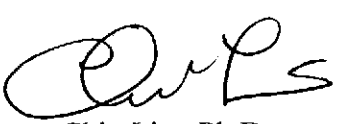
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Lin, Ph.D.
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 STATEMENT

510 (k) Number *(if known)* K032953

Device Name ***Embrace ™ WetBond ™ Restoration & PFM Repair Kit***

Indications for Use:

Embrace ™ WetBond ™ Restoration & PFM Repair Kit is a convenience kit used by dentists to repair restorations. The components were designed for bonding to all restorative, metal and ceramic surfaces, including precious and non-precious metals, porcelain and enamel. The kit provides materials to prepare, prime, protect, opaque, seal, finish and polish porcelain and restorative materials.

Susan Runner

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

510(k) Number: K032953

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use

(Per 21 CFR 801.109)