EXHIBIT 2 (REVISED)

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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

Telephone: 617-926-6666
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DEVICE NAME: ***Embrace™ WetBond™ Clear Sealant***

PREDICATE DEVICES:

Pulpdent *Embrace™ Pit and Fissure Sealant*
Pulpdent *Embrace™ Seal-n-Shine*
Dentsply *Delton Clear*
Bisco *BisCover*
Cosmedent *CosmeSeal*

DESCRIPTION AND INTENDED USE:

Embrace™ WetBond™ Clear Sealant is a hydrophilic, light-cured material recommended for use as a pit and fissure sealant. *Embrace™ WetBond™ Clear Sealant* may be used to seal small defects such as buccal pits, lingual grooves or facial surface defects. *Embrace™ WetBond™ Clear Sealant* may also be used as an orthodontic bracket coating. *Embrace™ WetBond™ Clear Sealant* hardens/cures such that the material is clear.

COMPARISON WITH PREDICATE PRODUCTS:

Embrace™ WetBond™ Clear Sealant is substantially equivalent in design, composition and intended use to the products listed above. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS:

Pulpdent Embrace™ WetBond™ Clear Sealant 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 872.3310 or 872.3765. The chemical ingredients used in *Embrace™ WetBond™ Clear Sealant* are the same as those used in the Pulpdent predicate products and equivalent to those used in the other products.

Four studies, carried out on similar products with the same Embrace™ WetBond™ resin base, demonstrate the effectiveness of Embrace™ WetBond™ materials.

- Penetration depth and marginal leakage of *Embrace™ WetBond™ Pit and Fissure Sealant and Small Lesion Restorative Material.* Professor Michael DeGrange, Biomaterials Innovations Research Development Laboratory, Paris, France. 2001, 2002.
- Microleakage of surface sealants in Class V restorations after thermal cycling. Pulpdent Corporation.
- In vitro study on toothpaste / toothbrush abrasion resistance of a new dental material: Seal-n-Shine. Pulpdent Corporation.
- Clinical performance of Embrace™ WetBond™ Pit and Fissure Sealant. Dr. JP O'Donnell. 2005.

There is no ISO or ANSI/ADA standard applicable to *Embrace™ WetBond™ Clear Sealant.* Laboratory testing has shown that *Embrace™ WetBond™ Clear Sealant* is equivalent in physical and mechanical properties to the predicate products. Four years of post-market surveillance of the two Pulpdent predicate products has demonstrated only positive feedback from our customers. There have been no serious complaints or failures and no injuries to patients or dental professionals. 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

FEB 8 2006

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

Re: K052281
Trade/Device Name: Embrace™ WetBond™ Clear Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC, EBD
Dated: January 31, 2006
Received: February 6, 2006

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.

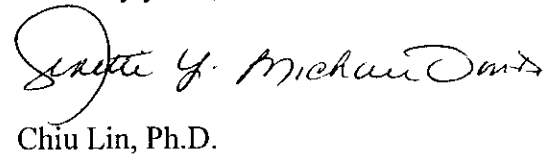
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number: K052281

Device Name: *Embrace™ WetBond™ Clear Sealant*

Indications for Use:

Embrace™ WetBond™ Clear Sealant is a hydrophilic, light-cured material recommended for use as a pit and fissure sealant. *Embrace™ WetBond™ Clear Sealant* may be used to seal small defects such as buccal pits, lingual grooves or facial surface defects. *Embrace™ WetBond™ Clear Sealant* may also be used as an orthodontic bracket coating. *Embrace™ WetBond™ Clear Sealant* hardens/cures such that the material is clear.

Prescription Use ✓ 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)

[illegible]
[illegible] of Anesthesiology, General Hospital,
[illegible] Control, Dental Devices

[illegible] Number K052281