

## EXHIBIT 2

K020432

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk  
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Watertown, MA 02472 USA

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**DEVICE:****Trade Name:** PULPDENT GLAZE**Classification Name:** Tooth Shade Resin Material**FDA Product Code:** 76 EBF, 21 CFR Part 872.3690**PREDICATE DEVICES:**

Pulpdent DenTASTIC UNO

Pulpdent Flows-Rite

UltraDent PermaSeal

UltraDent PermaQuick

Bisco Fortify

Kuraray Clear-Fil SE Bond

Kerr Opti Bond Solo Plus 3

**DESCRIPTION AND INTENDED USE:**

Pulpdent Glaze is a light-cured resin that contains no Bisphenol A and bonds tightly to enamel and composite restorations. Pulpdent Glaze is offered in different formulations to meet the needs of the dental professional: filled, unfilled, very low filler level, no fluoride and fluoride-releasing. Pulpdent Glaze can be used to seal composite surfaces, margins of restorations, cracks in teeth and restorations and to reduce micro-leakage. Two formulas can be used for dentin bonding.

**COMPARISON WITH PREDICATE PRODUCTS:**

**PULPDENT GLAZE** substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

**SAFETY AND EFFECTIVENESS:**

**PULPDENT GLAZE** 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 872.3690 or 872.3200. The chemical ingredients used in Pulpdent Glaze are used in two of the predicate products. Though there is no ISO or ANSI/ADA standard applicable to Pulpdent Glaze, laboratory testing has shown that Pulpdent Glaze 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...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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 17 2002

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

Re: K020432  
Trade/Device Name: Pulpdent Glaze  
Regulation Number: 872.3310  
Regulation Name: Coating Material for Resin Fillings  
Regulatory Class: II  
Product Codes: EBD, EBF, and KLE  
Dated: February 01, 2002  
Received: February 08, 2002

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.

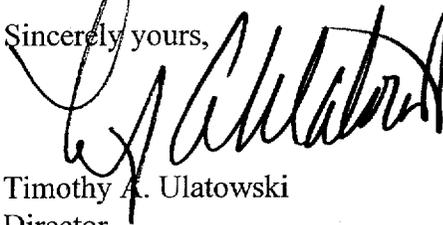
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### INDICATIONS FOR USE STATEMENT

510 (k) Number K020432  
(if known)

Device Name **PULPDENT GLAZE**

**Indications for Use:**

Pulpdent Glaze is a light-cured resin that contains no Bisphenol A and bonds tightly to enamel and composite restorations. Pulpdent Glaze is offered in different formulations to meet the needs of the dental professional: filled, unfilled, very low filler level, no fluoride and fluoride-releasing. Pulpdent Glaze can be used to seal composite surfaces, margins of restorations, cracks in teeth and restorations and to reduce micro-leakage. Two formulas can be used for dentin bonding.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use                        
(Per 21 CFR 801.109)

or

Over-The-Counter Use

Susan Brown  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K020432