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
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ken@pulpdent.com

DEVICE:
Trade Name: ***PULPDENT DENTITION INTEGRATING MATERIAL***
Classification Name: Sealant, Pit and Fissure, and Conditioner
FDA Product Code: 76 EBC, 21 CFR Part 872.3765

PREDICATE DEVICE:

Pulpdent Flows-Rite
Pulpdent Seal-Rite Pit and Fissure Sealant
Pulpdent Seal-Rite Low Viscosity Pit and Fissure Sealant
Pulpdent Seal-Rite UDMA
Kuraray Clear-Fil
Kerr OptiBond Solo Plus 3

DESCRIPTION AND INTENDED USE:

Dentition Integrating Material is a fluoride-releasing, light-cured, resin-based material that bonds tightly to dentition and is used to fill and seal the pits and fissures in teeth.

COMPARISON WITH PREDICATE PRODUCTS:

PULPDENT DENTITION INTEGRATING MATERIAL Is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above.

SAFETY AND EFFECTIVENESS:

PULPDENT DENTITION INTEGRATING 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 872.3690, 872.3765 or 872.3200. The chemical ingredients used in *Dentition Integrating Material* are used in the predicate products. Though there is no ISO or ANSI/ADA standard applicable to Dentition Integrating Material, laboratory testing has shown that *Dentition Integrating Material* 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

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

Re: K020287
Trade/Device Name: Pulpdent Dentition Integrating Material
Regulation Number: 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: January 23, 2002
Received: January 28, 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

K020287

INDICATIONS FOR USE STATEMENT

510 (k) Number **K 020287**

Device Name ***PULPDENT DENTITION INTEGRATING MATERIAL***

Indications for Use:

Pulpdent Dentition Integrating Material is a fluoride-releasing, light-cured, resin-based material that bonds tightly to dentition and is used to fill and seal the pits and fissures in teeth.

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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020287