

Pulpdent Triple-Cure™ Paste/Paste Resin Reinforced Glass Ionomer Cement

K030036

EXHIBIT 2

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

MAR 12 2003

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

Telephone: 617-926-6666
Fax: 617-926-6262

DEVICE

Trade Name: **PULPDENT Triple-Cure™ Paste / Paste Resin-Reinforced Glass Ionomer Cement**
Classification Name: Adhesive, Bracket and Tooth Conditioner, Resin
FDA Product Code: DYH, 21 CFR Part 872.3750

PREDICATE DEVICES

Pulpdent Triple-Cure™ Reinforced Glass Ionomer Orthodontic Cement
GC Fuji Ortho LC (light-cure)
GC Fuji Ortho Self-cure
Pulpdent Band-Rite

DESCRIPTION AND INTENDED USE

PULPDENT Triple-Cure™ Paste / Paste Resin-Reinforced Glass Ionomer Cement is used to adhere orthodontic brackets and bands to teeth, to cement metallic restorations and as a base and liner under restorations. It combines the advantages of a glass ionomer cement with the added strength of dental resin technology. *Triple-Cure™ Paste / Paste* is a fluoride-releasing, light-cure, self-cure, glass ionomer dental cement in two paste form. It is not recommended for post cementation or veneer cementation.

COMPARISON WITH PREDICATE PRODUCTS:

PULPDENT Triple Cure Paste / Paste is substantially equivalent in composition and intended use to the predicate products listed above. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS:

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. In addition, the predicate products listed above have been given 510 (k) premarket approval as Class II Dental Devices under CFR 872.3750.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2003

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

Re: K030036

Trade/Device Name: Pulpdent Triple-Cure™ Paste/Paste Resin
Reinforced, Glass Ionomer Cement

Regulation Number: 21 CFR 872.3750

Regulation Name: Bracket Adhesive Resin and Tooth Conditioner

Regulatory Class: II

Product Codes: DYH and EMA

Dated: December 27, 2002

Received: January 03, 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. 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) you may obtain. 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,



Susan Runner, DDS, MA
Interim 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 K030036
(if known)

Device Name *Triple-Cure™ Paste/Paste Resin-Reinforced Glass Ionomer Cement*

Indications for Use:

PULPDENT Triple-Cure™ Paste / Paste Resin-Reinforced Glass Ionomer Cement is used to adhere orthodontic brackets and bands to teeth, to cement metallic restorations and as a base and liner under restorations. It combines the advantages of a glass ionomer cement with the added strength of dental resin technology. *Triple-Cure™ Paste / Paste* is a fluoride-releasing, light-cure, self-cure, glass ionomer dental cement in two paste form. It is not recommended for post cementation or veneer cementation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use
(Per 21 CFR 801.109)

Kevin Mulvey for HSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number. K030036