

K0227341

## EXHIBIT 2

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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**DEVICE NAME:** PULPDENT CALCIUM HYDROXIDE PREPARATION

**PREDICATE DEVICES:** NEO / DIADENT VITAPEX CALCIUM HYDROXIDE PASTE  
ROEKO RSA RoekoSeal

**DESCRIPTION AND INTENDED USE:**

**PULPDENT CALCIUM HYDROXIDE PREPARATION** is a biocompatible polydimethylsiloxane-based root canal sealer used for the temporary and permanent filling of root canals after endodontic surgery. **PULPDENT CALCIUM HYDROXIDE PREPARATION** can be used on its own, in conjunction with Gutta Percha and for vital pulpectomies in deciduous teeth.

**COMPARISON WITH PREDICATE PRODUCTS:**

**PULPDENT CALCIUM HYDROXIDE PREPARATION** 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:**

General usage of the predicate products over about 5 years indicates a high benefit-to-risk ratio. See references below. There is no evidence of short-term or long-term risk or suspicion of any problems. In addition, the predicate products listed above have been given 510 (k) Premarket approval as Class II Dental Devices under CFR 872.3820. Please see Exhibit 4 for 510(k) numbers.

**REFERENCES:**

- Thomas AM, et al. Elimination of infection in pulpectomized teeth: a short-term study using iodoform paste. J. Endod. 1994 20(5): 233-5.
- Eda S, et al. Clinico-pathological studies on the healing of periapical tissues in aged patients by root canal filling using pastes of Calcium hydroxide added iodoform. Geriodontics 1985 1:98-104.
- Cohen S, Burns R. *Pathways of the Pulp*. 7<sup>th</sup> Ed. 1998 Mosby.
- Nurko C, Garcia-Godoy F. Evaluation of a Calcium hydroxide / iodoform paste (Vitapex) in root canal therapy for primary teeth. J. Clin Pediatr. Dent. 1999 23(4): 289-294.



OCT 07 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K022734

Trade/Device Name: Puldent Calcium Hydroxide Preparation  
Regulation Number: 21 CFR 872.3820(b)(1)  
Regulation Name: Root Canal Filling Resin  
Regulatory Class: II  
Product Code: KIF  
Dated: August 12, 2002  
Received: August 16, 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.

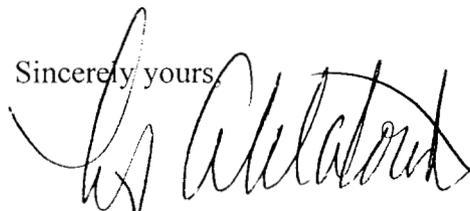
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 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)

K022734

Device Name: **PULPDENT CALCIUM HYDROXIDE PREPARATION**

### Indications for Use:

**PULPDENT CALCIUM HYDROXIDE PREPARATION** is a biocompatible polydimethylsiloxane-based root canal sealer used for the temporary and permanent filling of root canals after endodontic surgery. **PULPDENT CALCIUM HYDROXIDE PREPARATION** can be used on its own, in conjunction with Gutta Percha and for vital pulpectomies in deciduous teeth.

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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 Ranze

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

510(k) Number: K022734