PULPDENT CORPORATION K974398 *510k PREMARKET NOTIFICATION:* CAVITY VARNISH

EXHIBIT 2

FEB 18 1998

RESPONSE TO SMDA OF 1990

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Kenneth J. Berk
80 Oakland Street
PO Box 780
Watertown, MA 02272-0780 USA

TELEPHONE: (617) 926-6666
FAX: (617) 926-6262

DEVICE NAME: ***Pulpdent VARNISH I, II, III, IV***

PREDICATE DEVICES:

Pulpdent Polyamide Dentin Liner
Pulpdent Copal Varnish
Cetylite Zarosen
Cooley & Cooley Copalite Varnish

DESCRIPTION AND INTENDED USE:
Pulpdent VARNISH I, II, III, IV are desensitizing cavity varnishes and dentinal tubule sealers. They are indicated for exposed sensitive dentin or cementum after scaling, prophylaxis, cavity preparation and prior to any cementation and pin or post seating. ***Pulpdent VARNISH*** forms a hard protective coating which protects dentin and pulp, reduces acid diffusion from cements, minimizes marginal leaks and acts as a thermal insulator. This coating controls dentinal fluid flow by sealing the dentinal tubules and producing a physiologic barrier. It can be applied to all prepared cavities, to dentin and enamel, with or without the smear layer removed.

Pulpdent VARNISH is used by the dental professional to control thermal shock and sensitivity in teeth undergoing treatment or restoration. It can be used under veneers, inlays, crowns, onlays, amalgams and composite resins and to treat cervical or root sensitivity. ***Pulpdent VARNISH*** is a mixture of either copal resin or polyamide resin and strontium chloride in organic solvent. Formulas for Pulpdent Varnish III and IV also contain the surfactant cetyl pyridinium chloride.

COMPARISON WITH PREDICATE PRODUCTS:
Pulpdent VARNISH is substantially equivalent in composition and intended use to the predicate products. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS:
According to the scientific and clinical literature, use of cavity varnishes made from the materials present in ***Pulpdent*** Varnish have been effective and safe over about twenty years of experience. There is no evidence of short or long term risk or suspicion of any problems after literally billions of procedures in the United States. Please see Exhibit 8 for representative references.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1998

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02272-0780

Re: K974398
Trade Name: Pulpdent Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: November 17, 1997
Received: November 21, 1997

Dear Mr. Berk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): _____

Device Name: PULPDENT CAVITY VARNISH

Indications for Use:

Pulpdent VARNISH I, II, III, and IV are desensitizing cavity varnishes and dentinal tubule sealers. They are indicated for exposed sensitive dentin or cementum after scaling, prophylaxis, cavity preparation and prior to any cementation and pin or post seating. ***Pulpdent VARNISH*** forms a hard protective coating which protects dentin and pulp, reduces acid diffusion from cements, minimizes marginal leaks and acts as a thermal insulator. This coating controls dentinal fluid flow by sealing the dentinal tubules and producing a physiologic barrier. ***Pulpdent VARNISH*** is used by the dental professional to control thermal shock and sensitivity in teeth undergoing treatment or restoration. It can be applied to all prepared cavities, to dentin and enamel, with or without the smear layer removed. ***Pulpdent VARNISH*** can be used under veneers, inlays, crowns, onlays, amalgams and composite resins and to treat cervical or root sensitivity. ***Pulpdent VARNISH I, II, III and IV are*** mixtures of either copal resin or polyamide resin and strontium chloride in organic solvent. The formulas for ***Varnish III*** and ***IV*** also contain the surfactant, cetyl pyridinium chloride.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974198

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)