K993683

DEC 13 1999

EXHIBIT 2

RESPONSE TO SMDA OF 1990

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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

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

DEVICE NAME: ***PULPDENT UNO-DUO***

PREDICATE DEVICES: ***PULPDENT UNO***
PULPDENT DENTASTIC
Dentsply / Caulk *PRIME & BOND NT DUAL CURE*

DESCRIPTION AND INTENDED USE:

PULPDENT UNO-DUO is a kit containing *DenTASTIC UNO*, a single-component light cure dental primer / bonding resin [K 974014] and a *Dual Cure Catalyst* [K 926074, K 931710]. *PULPDENT UNO-DUO* is used by the dentist to bond to dentin, enamel, metals and resins in those situations in which he/she prefers a self-cure or dual cure product.

DenTASTIC UNO-DUO is based on the same technology from the American Dental Association (ADA) Health Foundation as *Pulpdent DenTASTIC* (Parts A, B and C) and *Pulpdent DenTASTIC UNO*. The formula for this product is based on research done by the ADA Health Foundation. Pulpdent manufactures *DenTASTIC* and *DenTASTIC UNO* under license from the ADA Health Foundation.

COMPARISON WITH PREDICATE PRODUCTS:

DenTASTIC UNO-DUO is substantially equivalent in composition and intended use to the above-mentioned predicate product. Please see Exhibit 5 for the entire comparison.

SAFETY AND EFFECTIVENESS:

All of the components used in *DenTASTIC UNO-DUO* have been used in legally marketed predicate dental devices.

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...[they] 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.

The effectiveness of this type of adhesive system is supported by research performed at the ADA Health Foundation, by research papers, and by evaluation by the editors of *Reality, 1999.* In addition, the predicate product listed above has been given 510 (k) Premarket approval as Class II Dental Devices under CFR 872.3690 Please see Exhibit 5 for full comparison and 510(k) numbers and Exhibit 10 for references.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 1999

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

Re: K993683
Trade Name: Pulpdent UNO-DUO
Regulatory Class: II
Product Code: KLE
Dated: October 22, 1999
Received: November 1, 1999

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

K993683

INDICATIONS FOR USE STATEMENT

510 (k) Number K993683
(if known)

Device Name PULPDENT DENTASTIC UNO-DUO KIT

Indications for Use:

PULPDENT DENTASTIC UNO-DUO is a kit containing *DenTASTIC UNO*, a single-component light cure dental primer / bonding resin [K 974014] and a *Dual Cure Catalyst* [K 926074, K 931710]. *PULPDENT UNO-DUO* is used by the dentist to bond to dentin, enamel, metals and resins in those situations in which a dual cure product is indicated.

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 K993683