EXHIBIT 2

MAR 19 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 Cavity Cleanser*** and ***PULPDENT Cavity Cleanser Plus***

PREDICATE DEVICES: Ultradent *UltraCid* and *UltraCid F*
Ultradent *Concepsis*
Dental Therapeutics AB
Tubulicid Plus
Tubulicid Blue Label
Tubulicid Red Label

DESCRIPTION AND INTENDED USE:
Pulpdent CAVITY CLEANSER is a dental product used to cleanse and moisten cavity preparations prior to sealing the dentin tubules or placing an adhesive that bonds to damp tooth structure. It can be used under veneers, inlays, crowns, onlays, amalgams and composite resins. Recent studies have suggested that this cleansing step reduces microleakage sensitivity in teeth undergoing treatment or restoration.

Pulpdent CAVITY CLEANSER PLUS combines all the features of ***Pulpdent CAVITY CLEANSER*** with the addition of sodium fluoride.

COMPARISON WITH PREDICATE PRODUCTS: ***Pulpdent CAVITY CLEANSER*** and **CAVITY CLEANSER PLUS** are substantially equivalent in composition and intended use to the predicate products. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS: The materials that make up these products are accepted by the Council on Dental Therapeutics and have been used safely in dental products for decades. Please see Exhibit 8 for the complete references.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1998

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

Re: K974202
Trade Name: Pulpdent Cavity Cleanser, Pulpdent Cavity Cleanser Plus
Regulatory Class: III
Product Code: LBH
Dated: January 29, 1998
Received: February 3, 1998

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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/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

510(k) Number (if known): K 974202

Device Name: PULPDENT CAVITY CLEANSER

Indications For Use:

DESCRIPTION AND INTENDED USE:

Pulpdent CAVITY CLEANSER is a dental product used to cleanse and moisten cavity preparations prior to sealing the dentin tubules or placing an adhesive that bonds to damp tooth structure. It can be used under veneers, inlays, crowns, onlays, amalgams and composite resins. Recent studies have suggested that this cleansing step reduces microleakage sensitivity in teeth undergoing treatment or restoration.

(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 K974202

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)