EXHIBIT 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

MAY 21 2009

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

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DEVICE:
Trade Name: *Pulpdent OraLube*
Classification Name:
Class:
FDA Product Code:

PREDICATE DEVICE:
Pulpdent Separating Medium K 896653

DESCRIPTION AND INTENDED USE:
Pulpdent OraLube is a water-soluble, viscous liquid coating intended to be used as an intraoral and perioral release agent, slip agent, lubricant, lip and skin protector in the following clinical situations:

- Taking an impression, in which OraLube is placed on the gums and inside the lip (areas not critical to the final outcome of the prosthesis) to facilitate the release of impression material and is applied to the lips and the skin around the mouth to prevent adherence of impression material;
- Using a dental cement or adhesive, in which OraLube is applied to adjacent hard and soft tissue and to the lips and skin around the mouth to prevent adherence of the cement or adhesive;
- Placement of a rubber dam, in which OraLube is brushed on the tooth to be treated to facilitate slipping the rubber dam over it.
- Long procedures, in which OraLube can be used to protect the lips from drying out and cracking.

COMPARISON WITH PREDICATE PRODUCTS:
Pulpdent OraLube is substantially equivalent in performance, intended use, safety and effectiveness to the predicate product listed above. The predicate product has been found substantially equivalent under the 510(k) Premarket Notification process under CFR 872.3690.

SAFETY AND EFFECTIVENESS:
Pulpdent OraLube is substantially equivalent in performance, intended use, safety and effectiveness to the predicate product listed above that has been on the market and used successfully by dental professionals for many years with no serious safety or effectiveness problems. *Pulpdent OraLube* is fabricated from materials that are often used in food.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2009

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

Re: K090457
Trade/Device Name: Pulpdent OraLube
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: ONK
Dated: February 18, 2009
Received: February 24, 2009

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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

510(k) Number: K 090457

Device Name: Pulpdent OraLube

Indications For Use:

OraLube is a water-soluble, viscous liquid coating intended to be used an intraoral and perioral release agent for the following clinical situations:

- Taking an impression, in which OraLube is placed on the gums and inside the lip (areas not critical to the final outcome of the prosthesis) to facilitate the release of impression material and is applied to the lips and the skin around the mouth to prevent adherence of impression material.
- Using a dental cement, in which OraLube is applied to the lips and skin around the mouth and to adjacent hard and soft tissue to prevent adherence of the cement;
- Placement of a rubber dam, in which OraLube is brushed on the tooth to be treated to facilitate slipping the rubber dam over it.
- Long procedures, in which OraLube can be used to protect the lips from drying out and cracking.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for ASR

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

510(k) Number: K090457