DEC - 9 2011

EXHIBIT 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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DEVICE

Trade Name: ***Activ Varnish***
Class: II

Classification Name: Cavity Varnish
FDA Product Code: 76LBH, 21 CFR Part 872.3260

PREDICATE DEVICES:

Pulpdent *Fluoride Varnish*
Ultradent *Flor-Opal Varnish White*
3M *Vanish 5% NaF White Varnish*
Colgate *Duraphat*
Voco *ReminPro*

DESCRIPTION AND INTENDED USE:

Activ Varnish is a resin-based varnish, containing 17% Xylitol and less than 20% ethanol, that is applied to enamel or dentin for professional treatment of dental hypersensitivity. *Activ Varnish* treats hypersensitivity by releasing fluoride, calcium and phosphorus ions that precipitate on and, thereby, occlude dentinal tubules and fill superficial, non-carious enamel lesions. *Activ Varnish* is available in unit-dose and bulk packaging.

COMPARISON WITH PREDICATE PRODUCTS:

Activ Varnish is substantially equivalent in design, composition, performance, and intended use to the predicate products:

Product	510(k) Number	Description	Intended Use	Composition
Pulpdent *Activ Varnish*		Resin-based fluoride varnish	To treat tooth hypersensitivity	Resin, Ethyl alcohol, Xylitol, Sodium fluoride, Calcium and Phosphate salts, Flavorant.
Pulpdent *Fluoride Varnish*	K093620	Resin-based fluoride varnish	To treat tooth hypersensitivity	Rosin, Ethyl lactate FCC, Sodium fluoride, Flavorant
Ultradent *Flor-Opal Varnish White*	K080249	5% sodium fluoride in a resin carrier	To treat tooth hypersensitivity	Natural resin, Alcohol, Xylitol
3M *Vanish 5% NaF White Varnish*	K880741	Resin-based fluoride varnish	To treat tooth hypersensitivity	Rosin ester, n-Hexane, Ethyl alcohol, Sodium fluoride, Thickener, Flavor and Color
Colgate *Duraphat*	K945794	Rosin-based fluoride varnish	To treat tooth hypersensitivity.	Rosin, Ethyl alcohol, Sodium fluoride, Water, Flavorant
Voco *ReminPro*	K101104	Hydroxyapatite and fluoride paste	Prevention and control of hypersensitivity	Calcium phosphate, Sodium fluoride, Xylitol

SAFETY AND EFFECTIVENESS:

Activ Varnish is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above that have been on the market and used successfully by dental professionals for more than 15 years with no serious safety or effectiveness problems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
P.O. Box 780
Watertown, Masachussets 02472

DEC - 9 2011

Re: K112946
Trade/Device Name: Pulpdent Activ Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: September 29, 2011
Received: October 6, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K112946

Device Name: *Pulpdent Activ Varnish*

Indications For Use:

Activ Varnish is a resin-based varnish, containing 17% Xylitol and less than 20% ethanol, that is applied to enamel or dentin for professional treatment of dental hypersensitivity. *Activ Varnish* treats hypersensitivity by releasing fluoride, calcium and phosphorus ions that precipitate on and, thereby, occlude dentinal tubules and fill superficial, non-carious enamel lesions.

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)

Susan Runner

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

510(k) Number: K112946