K022502

EXHIBIT 2

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
Email: Pulpdent@pulpdent.com

DEVICE NAME: ***PULPDENT PUTTY DAM***

PREDICATE DEVICES:

ULTRA DENT *OPAL DAM*
DEN-MAT *PAINT ON RUBBER DAM*
PREMIER *PERFECTA BLOCK OUT RESIN*
SHOFU *NIVEOUS LIQUID DAM*
LUMA LITE *LUMA BLOCK*
INTERDENT *FAST DAM*
BriteSmile *BARRIER MATERIAL*

DESCRIPTION AND INTENDED USE:

PULPDENT PUTTY DAM is a light-cured resin used by the dental professional during bleaching, air abrasion and etching procedures. *PULPDENT PUTTY DAM* protects soft tissue by creating a physical barrier.

COMPARISON WITH PREDICATE PRODUCTS:

PULPDENT PUTTY DAM is substantially equivalent in composition and intended use to the products listed above. Please see Exhibit 4 for the entire comparison.

SAFETY AND EFFECTIVENESS:

General usage of these materials over about 10 years indicates a high benefit-to-risk ratio. There is no evidence of short-term or long-term risk or suspicion of any problems. The safety and effectiveness of these resins is supported by the editors of *Reality, 2002.* In addition, the predicate products listed above have been given 510 (k) Premarket approval as Class I Dental Devices under CFR 872.4565 and 872.6300. Please see Exhibit 4 for 510(k) numbers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2002

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

Re: K022522
Trade/Device Name: Pulpdent Putty Dam
Regulation Number: 21 CFR 872.6300
Regulation Name: Rubber Dam and Accessories
Regulatory Class: I
Product Code: EIE
Dated: July 25, 2002
Received: July 30, 2002

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number *(if known)* K022522

Device Name ***PULPDENT PUTTY DAM***

Indications for Use:

PULPDENT PUTTY DAM is a light-cured resin used by the dental professional during bleaching, air abrasion and etching procedures. ***PULPDENT PUTTY DAM*** protects soft tissue by creating a physical barrier.

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)

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

510(k) Number: K022522