K962743

EXHIBIT 7

RESPONSE TO SMDA OF 1990

510(k)

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 Sodium Hypochlorite Solution***

PREDICATE DEVICE: *Premier* Hypogen
Union Broach Sodium Hypochlorite Solution

DESCRIPTION AND INTENDED USE:
Pulpdent SODIUM HYPOCHLORITE SOLUTION is a dental sodium hypochlorite solution used for root canal lavage and debridement and as an irrigant for root canal instrumentation. ***Pulpdent SODIUM HYPOCHLORITE SOLUTION*** is 5.25 % sodium hypochlorite in water.

COMPARISON WITH PREDICATE PRODUCTS:
Pulpdent SODIUM HYPOCHLORITE SOLUTION is substantially equivalent in composition and intended use as the predicate products. Please see Exhibit 5 for the entire comparison.

SAFETY AND EFFECTIVENESS:
According to the American Dental Association Council on Accepted Dental Therapeutics: "Sodium hypochlorite solution has a solvent action on pulp tissue and organic debris, and is used for irrigation of root canals. Aqueous solutions of 2.5 percent and 5 percent sodium hypochlorite are reportedly equally effective in dissolving pulpal debris when used as root canal irrigants." Sodium hypochlorite solution is considered safe in concentrations less than 7.5 percent and when applied to intact tissue. Please see Exhibit 6 for the entire citation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1996

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

Re: K962743
Trade Name: Pulpdent Sodium Hypochlorite Solution
Regulatory Class: Unclassified
Product Code: KJJ
Dated: July 9, 1996
Received: July 15, 1996

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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Acting 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):_____

Device Name: Pulpdent Sodium Hypochlorite Solution

Indications For Use:

Pulpdent SODIUM HYPOCHLORITE SOLUTION is a dental sodium hypochlorite solution used for lavage and debridement of root canals and as an irrigant for root canal instrumentation.. ***Pulpdent SODIUM HYPOCHLORITE SOLUTION*** is 5.25 % sodium hypochlorite in water.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010743

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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