

**EXHIBIT 7
RESPONSE TO SMDA OF 1990**

DEC 17 1997

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 DenTASTIC UNO*

PREDICATE DEVICES: *Pulpdent Dental Bond Enhancer (DenTASTIC)*
Bisco One Step
DenMat Tenure Quick
Dentsply/Caulk Prime and Bond 2.1

DESCRIPTION AND INTENDED USE:

Pulpdent DenTASTIC UNO is a single component dental adhesive primer and bond enhancer used by the dental professional to bond to dentin, enamel, metals and resins. The formula for *Pulpdent DenTASTIC UNO* is similar to that for Pulpdent Bond Enhancer [K926074, K931710, K953272, K953301] which was developed by the American Dental Association Health Foundation. The products are manufactured under license from that organization.

COMPARISON WITH PREDICATE PRODUCTS:

Pulpdent is substantially equivalent in composition and intended use to the above mentioned predicate products. Please see EXHIBIT 5 for the entire comparison.

SAFETY AND EFFECTIVENESS:

According to the NIH Technology Assessment Conference on Effects and Side-Effects of Dental Restorative Materials, "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio... [they]... are relatively trouble free. There is no evidence of short or long term risk...there is no suspicion of any problems after literally billions of procedures in the United States." Please see EXHIBIT 6 for the complete papers from the conference.

Furthermore, according to several research papers, this type of adhesive system (PMGDM adhesive monomer) is an effective and reliable adhesive for dentin and enamel. The results of independent laboratory and clinical studies demonstrate the bond strength of the Pulpdent formula (DenTASTIC) for this adhesive system. Please see EXHIBIT 6 for the complete papers.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1997

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02272-0780

Re: K974014
Trade Name: Pulpdent Dentastic Uno
Regulatory Class: II
Product Code: EMA
Dated: October 15, 1997
Received: October 22, 1997

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 (Pre-market 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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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

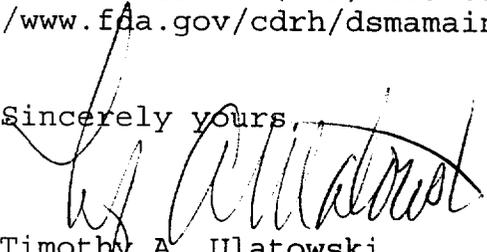
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. 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) 594-4618. 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/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): K974014

Device Name: DentASTIC UNO

Indications For Use:

Pulpdent DentASTIC UNO is a single component dental adhesive primer and bond enhancer used by the dental professional to bond to dentin, enamel, metals and resins.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974014

Prescription Use Yes
(Per 21 CFR 801.109)

CR

Over-The-Counter Use No

(Optional Format 1-2-96)