

K971594

SEP 12 1997

EXHIBIT 8

RESPONSE TO SMDA OF 1990

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 FLOW-RITE***

PREDICATE DEVICE: *Pulpdent OBA, Seal-Rite, Seal-Rite Low Viscosity,  
Pulpdent Hybrid Anterior Composite  
Bisco Aeliteflo  
E&D / Kerr Revolution*

DESCRIPTION AND INTENDED USE: ***Pulpdent FLOW-RITE*** is a visible light cured flowable composite material. It dispenses as a smooth paste with excellent working properties and translucency for matching, blending and depth of cure. It cures in 30-40 seconds, is color stable and polishes beautifully. Intended use: Class II, III, IV, and V restorations.

COMPARISON WITH PREDICATE PRODUCTS: ***Pulpdent FLOW-RITE*** is substantially equivalent in composition and/or 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...both composites and glass ionomers 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 12 1997

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

Re: K971594  
Trade Name: Flow-Rite  
Regulatory Class: II  
Product Code: EBF  
Dated: July 14, 1997  
Received: July 21, 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.

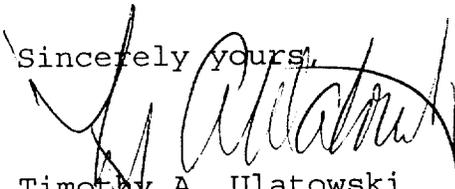
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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): K9715-94

Device Name: PULPDENT FLOW-RITE

Indications For Use:

**PULPDENT FLOW-RITE** is a visible light cured flowable composite used as a Class II, III, IV and V restorative. It dispenses as a smooth paste with excellent working properties and translucency for matching, blending and depth of cure. It cures in 30-40 seconds, is color stable and polishes beautifully.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Kanner

\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K971594

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)