

**JAN 31 2000**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Rolando Marasigan  
V.P. of Manufacturing  
Prime Dental Manufacturing, Incorporated  
3735 West Belmont Avenue  
Chicago, Illinois 60618

Re: K994224  
Trade Name: Prime-Dent Chemical Cure Composite  
Restorative Material  
Regulatory Class: II  
Product Code: EBF/KLE  
Dated: December 13 1999  
Received: December 15, 1999

Dear Mr. Marasigan:

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 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 pre-market notification submission does not affect any

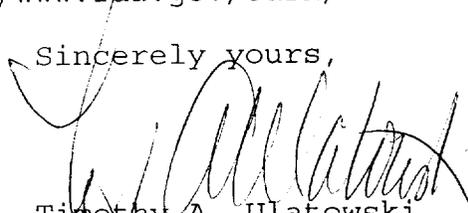
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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

K994224<sup>4-1</sup>

**Indications for Use**

**Prime-Dent** chemical cure composite restorative material is a Bis GMA thermosetting resin with inorganic radiopaque barium borosilicate and glass quartz particles ranging from .04-10 micron average. The kit consists of 15gm catalyst paste, 15gm base paste, 3cc enamel bond catalyst, 3cc enamel bond base, and 7.5 ml etchant.

**Prime-Dent** chemical cure composite restorative material is a direct filling dental composite used by licensed dentists to fill prepared cavities in teeth. Prime-Dent chemical cure composite restorative material is recommended for class III and class V restorations and for limited use in class I restorations in pre-molars and selected class IV restorations where esthetics are of primary importance.

PRESCRIPTION DEVICE

Susan Payne

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K994224