

2/05/99

K990135

**510K
SUMMARY**

Date Prepared 01/15/99

Submitted by Clark Smith D.M.D.

Kay-See Dental
124 East Missouri Avenue
Kansas City, MO 64106

Telephone 800-842-8844
Fax 816-842-3204

Contact Clark Smith D.M.D.

Trade name - Hydro-Cast Versa-Temp Non-Eugenol Provisional Cement

Common name - Temporary Cement

Classification Name - Dental Cement (872.3275)

Substantial equivalence claimed to - UNTIL eugenol free temporary polymeric composition cementing agent, K884081. Manufactured by SciPharm.

Description of the device.

The device is a syringe dispensing system that dispenses a eugenol free temporary dental cement

Intended use of device.

The eugenol free temporary dental cement is used to apply a temporary crown or bridge. It allows for an accurate seating, quick set, removal of excess material from work area , and a rigid set than can still be easily removed when the permanent is ready for application.

TECHNOLOGICAL CHARACTERISIC COMPARISON

SciPharm UNTIL

Hydro-Cast Versa Temp

1. Base: Preparation of bis-GMA
Multifunctional methacrylates,
polymerization initiator.

Base: Preparation of bis-GMA
Multifunctional methacrylates
polymerization activator.

2. Catalyst: Preparation of bis-GMA,
multifunctional methacrylates,
polymerization initiator.

Catalyst: Preparation of bis-GMA,
multifunctional methacrylates,
polymerization initiator.

Summary: The technological characteristics of the two devices are identical.

Discussion
NON-CLINICAL PERFORMANCE TESTING AND DATA

The critical performance characteristics of Hydro-Cast Versa-Temp Non-Eugenol Provisional Cement are Initial Set and Final set. Kay-See Dental performed test to assure the product performed to specification.

Specifications:

Initial Set - 90 sec +/- 30 sec

Final Set - 3 min +/- 30 sec

Test procedure:

Conditions - 75% humidity, 85 degree F

Sampling - 10 random subgroups of three samples each

The catalyst and base components were dispensed and mixed to obtain a .5 gram sample. Using an electronic stop watch, the samples were monitored for initial set (rubbery consistency) and then for final set (hardened material).

Test results:	Initial Set	Final Set
Min	80 sec	175 sec
Max	91 sec	196 sec

Conclusion:

The results of this testing provides additional assurance that Hydro-Cast Versa-Temp Non-Eugenol Provisional Cement does provide the important two stage cure and its performance is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1999

Clark Smith, D.M.D.
Executive Vice President
Kay-See Dental Manufacturing Company
124 East Missouri Avenue
Kansas City, Missouri 64106-1294

Re: K990155
Trade Name: Hydro-Cast Versa-Temp Non-Eugenol
Provisional Cement
Regulatory Class: II
Product Code: EMA
Dated: January 15, 1999
Received: January 19, 1999

Dear Dr. Clark

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

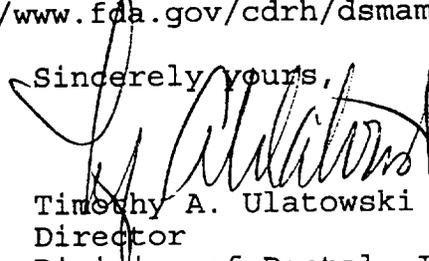
Page 2 - Dr. Clark

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,



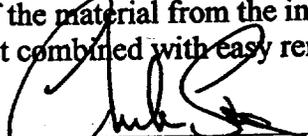
Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990155

STATEMENT OF INDICATIONS FOR USE

Hydro-Cast Versa-Temp Eugenol-Free Provisional Cement is used for temporarily adhering crowns and bridges. Hydro-Cast Versa-Temp provides for easy seating of the temporary, very fast first stage cure with an excellent consistency that allows the removal of the material from the interproximal areas, sulcular tissues and undercuts, and a rigid set combined with easy removal of the temporary.



Clark Smith D.M.D



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990155

Prescription Use 

(Per 21 CFR 801.109)