

OCT - 3 1997

K972844

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510 (k) Summary

Statement of Safety an Effectiveness

Kerr Temp Bond Clear Temporary Cement

Submitter

Sybron Dental Specialties Inc.
1717 West Collins Avenue
Orange, CA 92867
(714) 516-7486 - Phone
(714) 516-7488 - FAX
William R. Pike - Contact Person

Device Name

Trade Name: Temp Bond Clear
Common Name: Temporary Crown and Bridge Cement
Classification Name: Dental Cement Other than Zinc Oxide - Eugenol 76 EMA 2
(21 CFR 872.3275)

Devices for which Substantial Equivalence is Claimed

Temp Bond and Temp Bond NE (Non Eugenol) : Manufactured by Kerr Corporation
Resiment Resin Based Temporary Cement : Marketed by Septodont Corp.

BACKGROUND

Provisional or temporary restorative materials are used in dentistry for treatment procedures not intended to be permanent or final. The purpose of the temporary material is to protect a prepared tooth surface during the interim period until the permanent restoration is available. An example of this interim period is the time that passes while porcelain or metal prosthetic devices are being fabricated in a dental laboratory. Another purpose of a temporary restoration is to provide an esthetically pleasing appearance for the patient during this interim period. It is necessary to attach the temporary device with a cement that is durable enough to withstand forces encountered in the oral environment yet is easily removed when the permanent appliance becomes available. Zinc Oxide/Eugenol (ZOE) type cements have been the most popular with dentists in the past for this application, however, with the advent advanced resin-based restorative materials a resin-based, glass reinforced cement has been developed to overcome the shortcomings of the ZOE cements.

TEMP BOND CLEAR TEMPORARY CEMENT

Kerr's Temp Bond Clear is designed to fulfill all of the requirements of a successful temporary restorative cementation material. These requirements are itemized below:

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1. **Ease of placement.** Kerr Temp Bond Clear handles very similarly to the ZOE cements already familiar to dentists.
2. **Convenience.** The chemical cure characteristics of Temp Bond Clear provide for a quick and simple procedure.
3. **Aesthetics.** The highly translucent nature of Temp Bond Clear provides a pleasing, tooth-like appearance even when margins are exposed.
4. **Strength.** The glass reinforced resin resists mastication forces that would fracture a ZOE type cement.

SAFETY

The safety of Kerr Temp Bond Clear has been demonstrated by subjecting cured samples of the material to various types of biocompatibility tests as recommended in the ISO 10993 biocompatibility guidance standard. These tests were conducted by an independent laboratory which specializes in safety and toxicity evaluation. The tests include:

1. Ames Mutagenicity Assay
2. Cytotoxicity Study (Agarose Overlay)

EFFICACY

Effectiveness or suitability to the intended purpose of Kerr Temp Bond Clear has been demonstrated by a combination of in-house testing and side by side test comparisons to predicate devices currently on the market. Results of this bench testing indicates that Kerr Temp Bond Clear Temporary Cement performs as well or better than predicate devices currently on the market. An demonstration of this fact is presented in the comparison of Temp Bond Clear with Temp Bond (ZOE) below.

<u>PROPERTY</u>	<u>Temp Bond Clear</u>	<u>Temp Bond (ZOE)</u>
Diametral Tensile Strength @ 24 hr.	4285 psi	280 psi
Water Solubility	0.5 %	2.5 %
Film Thickness	< 25 microns	< 25 microns
Fluoride Release Rate	10 ...µg/cm ² /day	0



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 3 1997

Mr. William R. Pike
Regulatory Affairs Specialist
Kerr Dental Materials Center
1717 West Collins Avenue
Orange, California 92667

Re: K972844
Trade Name: Temp Bond Clear
Regulatory Class: II
Product Code: EMA
Dated: September 16, 1997
Received: September 22, 1997

Dear Mr. Pike:

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

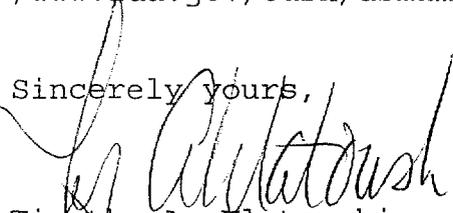
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Product Radiation Control provisions, or other Federal laws or regulations.

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 : K 972844

Device Name : Kerr Temp Bond Clear Temporary Cement

Indications For Use : Kerr Temp Bond Clear Temporary Cement is indicated for use for temporary crown and bridge cementation procedures.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 972844

Prescription Use _____
(Per 21 CFR 801.109)