

OCT 1 1999

K992292

## 510(K) Summary

**Date:** June 30, 1999

**Address:** Heraeus Kulzer, Inc.  
4315 S. Lafayette Blvd.

**Contact:** Cheryl V. Zimmerman  
219-299-6662

**Device:** GLUMA COMFORT BOND + Desensitizer

### Substantially Equivalent to:

Bond -1 (Jeneric/Penetron Incorporated, Wallingford, CT)  
ALL Bond 2 (BISCO)  
3M Single Bond Dental Adhesive (3M)  
One Step Dental Adhesive

### Device Description:

GLUMA COMFORT BOND + DESENSITIZER is a one bottle adhesive, designed to bond resinous restorative materials to dental hard tissue. It is an extension of the Gluma One Bond bonding system family. The product is a light curing monomer mixture dissolved in ethanol which, following conditioning with phosphoric acid, is applied to enamel and dentin prior to co- polymerization with the restorative. When compared with conventional bonding agents the main advantage of such simplified bond mediators is their reliability and ease of use in the dental office.

The composition of GLUMA COMFORT BOND + DESENSITIZER is based on three monomers which individually have been used in marketed dental products for decades. The hydrophilic hydroxyethylmethacrylate (HEMA) is essential for perfect wetting of and penetration into the conditioned tooth structure. Similarly, 4-MET(A) has hydrophilic and moieties for wetting and polymerization, whereas the urethane di-methacrylate monomer is responsible for formation of a cross-linked polymer network. The ethanol has the function of a carrier for the monomers while being an effective water chaser at the same time. The addition of glutaraldehyde to the Gluma One Bond formula allows the dental

practitioner to obtain the complete desensitizing and other effects of Gluma Desensitizer and the bonding of Gluma One Bond all from one bottle. The combination of glutaraldehyde and HEMA in Gluma Desensitizer penetrates the dentinal tubules to a depth of 200 $\mu$ m, setting up multiple walls that block the flow of fluids in the tubules. This immediately eliminates dentinal tubule-caused hypersensitivity. In addition, it has been found that glutaraldehyde bonds covalently to the collagen fibers, aiding re-wetting and resulting in reduced marginal contraction gap.

The application procedure is very easy. The solution is applied in small amounts to the conditioned moist tooth surface with two to three consecutive strokes, the water and ethanol is eliminated by a gentle air blast and finally, the resin is light cured for 20 seconds. Thorough in-vitro investigation has proven that the GLUMA COMFORT BOND + DESENSITIZER performs better than or at least as good as the leading resinous bonding systems available in the market. GLUMA COMFORT BOND + DESENSITIZER is also proven to bond to non-precious dental alloys, such as CoCr-based casting alloy and amalgam.

Based on this evidence and the cytotoxicity data, GLUMA COMFORT BOND + DESENSITIZER is recommended as an effective enamel/dentin adhesive when used in accordance with the instructions for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 1 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Cheryl V. Zimmerman  
Heraeus Kulzer, Incorporated  
Dental Products Division  
4315 South Lafayette Boulevard  
South Bend, Indiana 46614-2517

Re: K992292  
Trade Name: GLUMA COMFORT BOND and Desensitizer  
Regulatory Class: II  
Product Code: KLE  
Dated: July 5, 1999  
Received: July 7, 1999

Dear Ms. Zimmerman:

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 legally marketed predicate 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.

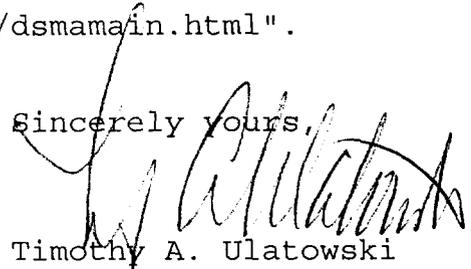
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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) 594-4692. 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" (21CFR 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/dsma/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):

Device Name: Gluma Comfort Bond+ Desensitizer

Indications For Use:

*Gluma Comfort Bond + Desensitizer is a light curing single component enamel/dentin adhesive for bonding of all current brands of resin composite restorative materials and compomers. It also provides adhesion to metals such as amalgam. Gluma Comfort Bond + Desensitizer combines primer and adhesive in a single bottle.*

*Serves as a desensitizer/preventative in dentin hypersensitivity conditions by means of sealing exposed dentinal tubules which effectively blocks the fluid flow in the tubules that cause sensitivity.*

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

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Concurrence of CDRH, Office of Device evaluation (ODE)

*Suzer R. Moore*

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K992242

Prescription Use ✓ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)