

K992985

Heraeus Kulzer, Inc.
South Bend, IN. 46614
GLUMA COMFORT BOND 510(K)

OCT 14 1999

510(K) Summary

Date: August 19, 1999

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

Contact: Cheryl V. Zimmerman
219-299-6662

Device: Gluma® Comfort Bond

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 One Bond, available since October, 1998, has been proven to be an excellent, one-bottle bonding system. In independent testing¹, Gluma One Bond had shear bond strength scores of 25.4 MPa to dentin and 35.1 MPa to enamel. In addition, all six fillings in the test were gap-free. The *REALITY* evaluation organization gave Gluma One Bond four stars, making it a *REALITY'S Choice*, calling it a "highly effective adhesive," due to its "proven ingredients." Their tests "found its bond strengths are quite comparable to Prime & Bond 2.1."²

Of particular interest in Gluma One Bond is 4-META. 4-META is a well known and proven chemical substance used in dentistry for many years. 4-META, besides adding to the strength of the bond to composites, also allows bonding to amalgam and other non-precious metal alloys.

The acetone in the Gluma One Bond has been replaced with ethanol and the product name changed to Gluma Comfort Bond. Gluma Comfort Bond is a one bottle adhesive, designed to bond resinous restorative materials to dental hard tissue. This product will provide the strength of 4-META and the ability to do a traditional 2-3 second drying after etching.

The composition of Gluma Comfort Bond 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-META has hydrophilic 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.

An early shear bond strength test¹ of Gluma Comfort Bond indicates scores of 25.1 ± 3.5 MPa to dentin and 30.8 ± 6.1 MPa to enamel. In addition, five of the six fillings in the test were gap-free.

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. GLUMA COMFORT BOND is also proven to bond to non-precious dental alloys, such as CoCr-based casting alloy and amalgam.

¹ Testing method described in "Laboratory evaluation of one-component enamel/dentin bonding agents," Finger W.J., Fritz U., *Am J Dent* 1996; 9:206-210

² REALITY. Volume 13. Houston, TX: REALITY Publishing; 1999



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Ms. Cheryl V. Zimmerman
Manager, Quality Operations & Regulatory Affairs
Heraeus Kulzer, Inc.
4315 South Lafayette Boulevard
South Bend, Indiana 46614-2517

Re: K992985

Trade Name: Gluma® Comfort Bond
Regulatory Class: II
Product Code: KLE
Dated: September 2, 1999
Received: September 3, 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 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

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South Bend, IN. 46614
GLUMA COMFORT BOND 510(K)

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510(k) Number (if Known): K992985

Device Name: Gluma® Comfort Bond

Indications For Use:

GLUMA® Comfort Bond is a light curing single component bonding agent use in restorative adhesive dentistry specifically developed for bonding resin-based filling materials (e.g. composites, compomers, Polyglas®) to hard dental tissues. Other indications include bonding of amalgam and laboratory-produced restorations. GLUMA® Comfort Bond permits priming and bonding to be carried out in single step.

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

Concurrence of CDRH, Office of Device evaluation (ODE)

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

(Optional Format 1-2-96)

Susan Powell
(Division Sign-Off)
Division of **Dental, Infection Control,**
and **General Hospital Devices**
510(k) Number K992985