5/25/99

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

K990143

Statement of Safety and Effectiveness

GLUMA ONE BOND is a one bottle adhesive, designed to bond resinous restorative materials to dental hard tissue. The product is a light curing monomer mixture dissolved in acetone 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 ONE 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-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 organic solvent acetone has the function of a carrier for the monomers while being an effective water chaser at the same time.

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 acetone 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 ONE BOND performs better than or at least as good as the leading resinous bonding systems available in the market. GLUMA ONE BOND is also proven to bond to non-precious dental alloys, such as CoCr-based casting alloy and amalgam.

The results of a short-term clinical observation done by eight dentists under regular office conditions, on some more than 300 restorations bonded with GLUMA ONE BOND confirms that the product is easy to use, safe, and effective. Based on this evidence and the very promising in vitro data, GLUMA ONE BOND 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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1999

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

Re: K990143
Trade Name: Gluma One Bond
Regulatory Class: II
Product Code: KLE
Dated: January 12, 1999
Received: January 19, 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

K990143

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

(Predicate
510(k) Number (if Known): K974300 K974390)

Device Name: *Gluma One Bond*

Indications For Use:

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)

Concurrence of CDRH, Office of Device evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990143

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

(Optional Format 1-2-96)