

JUL 10 1998

K981524

Date: July 2, 1998

**510(K) Summary**

**Submitter: Gresco Products, Inc.**  
13391 Murphy Rd.  
Stafford, TX 77477  
(281)261-1811

**Contact person: Clinton D. Vaupel**  
**Device name: Prilane**  
**Common name: Silane Coupler**  
**Classification name: Unknown**

Prilane is substantially equivalent to Fusion marketed by Geo Taub Co. and Gerinate Prime marketed by Denmat. Both products were marketed prior to May 28, 1976. Both of the above products are silane couplers. These products are similar chemically but differ in that they must be hydrolyzed prior to use.

Scotch Prime, 510(K) number K853698, marketed by 3M is very similar to Prilane. Both are prehydrolyzed and ready to use in the purchased state. Both use isopropanol as a vehicle.

**Description:** Prilane is a silane coupler, a device that when applied to inorganic surfaces such as dental porcelain, will chemically bond to the porcelain and will then bond to the organic thermoset resins that are commonly used as luting agents and restorative materials in dentistry.

**The above results in:**

- Improved adhesion.
- Increased composite wet & dry strength.
- Increased composite wet & dry flexural strength.

Prilane is a clear, low viscosity liquid having a pH of 6. Prilane is a prehydrolyzed silane. The hydrolyzation involves adding a small amount of water (.125%) to the silane. The hydrolyzation reaction causes the silane to be both organic and inorganic reactive. The silane material is Dow Corning Z-6030 which is  $\gamma$ -methacryloxypropyltrimethoxy silane.

**intended use:** There are two(2) intended uses of Prilane.

**1. Repair of fractured porcelain:**

Occasionally dental restorations that are made of porcelain will chip or

fracture. When this happens, many times the dentist prefers to repair the fracture rather than replacing it with a new crown or bridge.

This repair procedure involves the following steps.

- a. Etch porcelain with porcelain etchant.
  - b. Apply Prilane or other silane to porcelain surface and dry.
  - c. Apply Bis-Gma unfilled resin over Prilane or other silane.
  - d. Apply Bis-Gma Restorative Resin over unfilled resin and light cure.
2. Bonding all porcelain restorations:

Many dental restoration are now made totally of dental porcelain. This type of restoration is always bonded with a composite luting resin. To insure that the best possible adhesion is achieved, Prilane or other silane is used as one of the steps.

The all porcelain bonding steps are:

- a. Etch porcelain with porcelain etchant.
- b. Etch tooth with tooth etchant.
- c. Apply Prilane or other silane to etched porcelain interface and air dry.
- d. Apply Bis-Gma unfilled resin to porcelain interface.
- e. Apply Bis-Gma unfilled resin to etched tooth surface.
- f. Apply Bis-Gma Luting Cement to interface of porcelain restoration.
- g. Seat porcelain on tooth to be restored

Prilane as stated earlier is similar to several legally marketed devices. All of these devices are chemically similar. All are used for the same purpose and all use a common silane raw material vendor. That vendor being Dow Corning.

Prilane is never used on living tissue.

Silane materials have been used by dentists for over 25 years in millions of applications with, to the best of our knowledge never an adverse or toxic reaction.



JUL 10 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Clinton D. Vaupel  
President  
Gresco Products, Incorporated  
13391 Murphy Road  
Stafford, Texas 77477

Re: K981524  
Trade Name: Prilane  
Regulatory Class: II  
Product Code: EIH  
Dated: May 29, 1998  
Received: June 1, 1998

Dear Mr. Vaupel:

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.

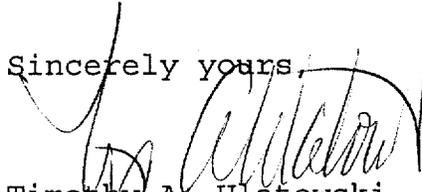
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

K981524

510(K) number: K981524

Device name: Prilane

Indications for use:

Prilane is indicated as part of a system to repair fractured dental porcelain and to bond all porcelain restorations.

The system involves etching the porcelain and then applying a small amount of Prilane to the etched surface.



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

510(k) Number K981524

3