

510 (k) Summary

K972858

Statement of Safety an Effectiveness

SEP 26 1997

Kerr Nexus One Bottle Adhesive

Submitter

Sybron Dental Specialties Inc.
1717 West Collins Avenue
Orange, CA 82867
(714) 516-7486 - Phone
(714) 516-7488 - Fax
William R. Pike - contact Person

Device Name

Trade Name: Not yet Determined

Common Name: One Bottle direct and indirect all-purpose dental adhesive

Classification Name: Resin Tooth Bonding Agent, 76KLE, Class II, CFR872.3200

Classification: Dental Device Panel

Devices for which Substantial Equivalence is claimed

Prime & Bond 2.1 (Product of Dentsply International Inc.)

One-Step (Product of BISCO, Inc.)

Background

Kerr Nexus One Bottle Adhesive is an all purpose dental adhesive consisting of a visible light curable methacrylate resin based mixture of monomers capable of forming both chemical and mechanical adhesive bonds to natural tooth structures (enamel and dentin) and to commonly used restorative materials (composite resin, porcelain and metals). It is supplied as a one bottle, single step dental adhesive that is simple to use and produces fast, strong adhesion suitable for all commonly used restorative techniques. The organic solvent component allows the application of the adhesive to flow into micro-fissures of the substrate smoothly and when the fast evaporating solvent is removed a thin resin layer remains to form a tight bonding interface between tooth and restorative materials.

Kerr/Dental Materials Center currently manufactures a product marketed under the Trade name Nexus Universal Luting System (510 (k) Reference K954762). It is used by dentist to cement pre-fabricated restoration to the tooth. Kerr Nexus one bottle system is simply

) the replacement of the existing three-bottle system into one bottle system. This is a product based on the requests from the customers for a simple bonding system.

Safety

The safety of Kerr Nexus One Bottle Adhesive has been demonstrated by subjecting cured samples of the adhesive 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. No unknown chemical component is used in this device.

Independent Laboratory Evaluation by Toxicon Corporation

- A.) Cytotoxicity Study (MEM Elution Method USP23)
- B.) Mutagenicity : Salmonella Typhimurium REVERSE MUTATION ASSAY
(Ames Test)

EFFICACY

) Effectiveness or suitability to intended purpose of Kerr Nexus One Bottle Adhesive has been demonstrated by a combination of in-house testing and side by side test comparisons to predicate products currently on the market. Results of this bench testing indicates that Kerr Nexus One Bottle Adhesive performs as well or better than **PRIME & BOND 2.1 and ONE-STEP**, two predicate devices currently on the market and being represented as one step all-purpose dental adhesives.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 26 1997

Mr. William R. Pike
Regulatory Affairs Specialist
Sybron Dental Specialities, Incorporated
1717 W. Collins Avenue
Orange, California 92667

Re: K972858
Trade Name: Kerr Nexus One Bottle Adhesive
Regulatory Class: II
Product Code: KLE
Dated: August 4, 1997
Received: August 4, 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.

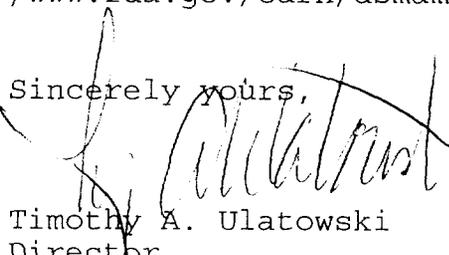
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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) 594-4618. 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

