K971760

SEP 12 1997

510 (k) Summary

Statement of Safety an Effectiveness

BelleGlass HP Enamel Repair Material

Submitter

Sybron Dental Specialties Inc.
1717 West Collins Avenue
Orange, CA 92867
(714) 516-7486 - Phone
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William R. Pike - Contact Person

Device Name

Trade Name: BelleGlass HP Enamel Repair Material
Common Name: Dual Cured Composite Crown and Bridge Fabrication Material
Classification Name: Tooth shade resin material, Class II, 21 CFR 872.3690

Devices for which Substantial Equivalence is Claimed

BelleGlass HP Heat and Pressure Cure Enamel Repair Material (Kerr Corporation)

BACKGROUND

Kerr/Dental Materials Center currently manufactures a product marketed under the Tradename **BelleGlas HP Dental Laboratory Crown and Bridge Fabrication System** (510 (k) Reference K955331). It is used in commercial dental laboratories to fabricate composite based crowns and bridgework. This product has been on the market since March, 1996. A component material in the current product is a heat + pressure cured enamel repair to be used for minor adjusments or repairs to appliances damaged during processing. BelleGlass Dual Cure Enamel Repair Material is simply a reformulation of the heat and pressure cure material to allow the material to be light cured so that it is more stable during the transfer to the Heat + Pressure Curing Device. This is a product modification based on requests from customers for a more durable, with respect to paste deformation and flow, during the transfer procedure.

BelleGlass HP Dual Cure Enamel Repair Material

A very small amount of photoinitiating agent (< 1 %) was added to the formula and the directions will be rewritten to include the light cure step when using the enamel repair materials.

SAFETY

The reformulated product was reexamined using two of the test protocols specified in the ISO 10993 Biocompatibility Testing Guidance Standard.

The testing consisted of the following:

Independent Laboratory Evaluation by Toxicon Corporation

A.) Cytotoxicity: Agar Diffusion Test - USP

B.) Mutagenicity: *Salmonella Typhimurium* REVERSE MUTATION ASSAY (Ames Test)

EFFICACY

Effectiveness or suitability to the intended purpose of **BelleGlass HP Dual Cure Enamel Repair Material** has been demonstrated by side by side test comparisons to the current heat and prssure cure enamel repair material. Results of this bench testing indicates that the dual cure material performs as well or better than the heat + pressure cured material. Actual results of this comparative testing is provided elsewhere in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 1997

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

Re: K971762
Trade Name: Belleglass HP Enamel Repair Material
Regulatory Class: II
Product Code: EBF
Dated: July 17, 1997
Received: July 21, 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 (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 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 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) 594-4618. 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

510 (k) Number : K 971762

Device Name : BelleGlass Dual Cure Enamel Repair Resin

Indications For Use : BelleGlass Dual Cure Enamel Repair Resin is indicated for use with the BelleGlass HP Heat + Pressure Cure Composite Crown and Bridge Fabrication System when it is necessary to perform minor adjustments or repairs to an appliance during the fabrication procedure.

Concurrence of CDRH, Office of Device Evaluation

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971762

prescription use Yes

over-the-counter use No