SYBRON DENTAL SPECIALTIES

APR 2 8 2006

K060472

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
100 Bayview Circle, Suite 6000
Newport Beach, California 92660
(949) 255-8766 - Phone
(949) 255-8763 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: February 2006

Device Name:

- Trade Name - *Premise Flowable*
- Common Name - Light-Curable Dental Restorative Material
- Classification Name - Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Point 4 Flowable*

Device Description:

Premise Flowable is a nano-filled, light-cure, resin restorative material dispensed in a syringe with single-use tips. Premise Flowable uses pre-polymerized filler and nanofillers combined with proven Point 4 technology to deliver strength and durability.

Intended Use of the Device:

The intended use of *Premise Flowable* is for use as a filling material for Class I - V restorations. Additional functions include: base/liner material, repair of enamel defects, repair of temporaries, repair of porcelain restorations, minor occlusal build-ups in non-stress bearing areas, pit and fissure sealant, cement for ceramic/composite veneers, incisal abrasions, and core build-ups.

Substantial Equivalence:

Premise Flowable is substantially equivalent to other legally marketed devices in the United States. The composite restorative material marketed by Kerr Corporation functions in a manner similar to and is intended for the same use as the product manufactured by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kerr Corporation
C/O Ms. Colleen Boswell
Sybron Dental Specialties
100 Bayview Circle Suite 6000
Newport Beach, California 92660

APR 28 2006

Re: K060472
Trade/Device Name: Premise Flowable
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: February 22, 2006
Received: February 23, 2006

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

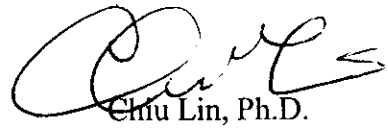
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I

Indications for Use

510(k) Number (if known): K060472

Device Name: *Premise Flowable*

Indications For Use:

Premise Flowable is a nano-filled, light cure, resin dental restorative suitable for Class I - V restorations. Additional functions include: base/liner material, repair of enamel defects, repair of temporaries, repair of porcelain restorations, minor occlusal build-ups in non-stress bearing areas, pit and fissure sealant, cement for ceramic/composite veneers, incisal abrasions, and core build-ups.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...Dental Devices

K060472