K093484

SYBRON DENTAL SPECIALTIES

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

JAN 27 2010

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7472 - Facsimile
Wendy Garman - Contact Person

Date Summary Prepared: November 2009

Device Name:

- Trade Name – Premise Flowable Modified
- Common Name – Dental Composite Restorative Material
- Classification Name – Tooth Shade Resin Material, per 21 CFR § 872.3690

Devices for Which Substantial Equivalence is Claimed:

- Kerr Dental Materials Center, *Premise Flowable*

Device Description:

Premise Flowable Modified is a medium viscosity, light-cured, nano filled, resin restorative material, dispensed in a syringe with single-use tips. It is suitable for Class I - V restorations. This nano composite technology incorporates three different fillers resulting in a flowable, yet sculptable and non-slumping material.

Intended Use of the Device:

The intended use of *Premise Flowable Modified* is for use as a 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 area, pit and fissure sealant, cement for ceramic/composite veneers, incisal abrasions and core build-ups.

Substantial Equivalence:

Premise Flowable Modified is substantially equivalent to other legally marketed devices in the United States. *Premise Flowable Modified* functions in a manner similar to and is intended for the same use as *Premise Flowable* that is currently marketed by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kerr Corporation
C/O Ms. Wendy German
Sybron Dental Specialties, Incorporated
Kerr Corporation
1717 West Collins Avenue
Orange, California 92867

JAN 27 2010

Re: K093484
Trade/Device Name: Premise Flowable Modified
Regulation Number: 21CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: November 6, 2009
Received: November 9, 2009

Dear Ms. Garman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093484

Device Name: *Premise Flowable Modified*

Indications For Use:

Premise Flowable Modified 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 area, 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)

R Betz DDS for Dr. K. P. Mulay

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

510(k) Number: K093484