DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 5, 2015

Sybron Dental Specialties
Ms. Kerri Casino
Regulatory Affairs Manager
1717 West Collins Avenue
Orange, California 92687

Re: K143209
Trade/Device Name: SonicFill 2
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF, EBC
Dated: November 7, 2014
Received: November 10, 2014

Dear Ms. Casino:

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 contact 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. 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143209

Device Name
SonicFill 2

Indications for Use *(Describe)*

SonicFill 2 is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include: base/liner material, repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups, pit and fissure sealant, luting of composite/ceramic veneers, core build-ups and incisal abrasions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY for SonicFill 2

SonicFill 2

1. Submitter Information:

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92687

Contact Person: Kerri Casino
Telephone Number: 714-516-7634
Fax Number: 714-516-7472

Date Prepared: January 16, 2015

2. Device Name:

- Proprietary Name: SonicFill 2
- Classification Name: Tooth Shade Resin Material
- CFR Number: 872.3690
- Device Class: II
- Product Code: EBF, EBC

3. Predicate Device:

SonicFill 2 is substantially equivalent to the legally marketed device Metamorphosis (K091023) cleared on May 21, 2009, product code EBF, EBC.

4. Description of Device:

SonicFill 2 is a light-cured, low-shrink, resin-based, dental restorative designed for direct placement. SonicFill 2 is used in combination with the SonicFill 2010 Handpiece (K091091), which activates the restorative sonically for delivery. Upon delivery the restorative drops in viscosity, allowing the composite to closely adapt to the cavity walls. When the cavity is filled and the SonicFill 2010 Handpiece (K091091) is deactivated, the restorative resin returns to its original viscosity. The composite in the cavity is then shaped and sculpted to the contours of the tooth. SonicFill 2 is designed to have a high depth of cure and low shrinkage stress allowing a cavity up to 5mm in depth to be filled and cured in a single bulk increment.

5. Statement of Intended Use:

SonicFill 2 is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include: base/liner material, repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups, pit and fissure sealant, luting of composite/ceramic veneers, core build-ups and incisal abrasions.

6. Identification of Risk Analysis Method

Risk analysis was performed on SonicFill 2 utilizing a process based on ISO 14971:2007. The results of the risk analysis performed on SonicFill 2 concluded that all device design controls and process controls will be able to mitigate known potential failures and effects. In addition, performance testing and biocompatibility testing were performed to mitigate other potential risks.

7. Description of Safety and Substantial Equivalence:

Technological Characteristics

The technological characteristics of SonicFill 2 are very similar to those of the predicate, Metamorphosis (K091023). Both composites are sonically activated using the SonicFill SonicFill 2010 Handpiece (K091091) during delivery. Both SonicFill 2 and Metamorphosis (K091023) composites behave in the same manner in terms of viscosity dropping during activation while adapting to the cavity, and viscosity increasing after activation ends. Both SonicFill 2 and Metamorphosis (K091023) use the same SonicFill 2010 Handpiece (K091091) and the same unidose delivery system.

Non-Clinical Performance Data

Non-clinical performance data included testing for mechanical strength, polishability, water sorption and solubility, flexural strength, depth of cure, light sensitivity, radiopacity, volumetric shrinkage, shrinkage stress, and color stability. Working Time testing, stability testing and biocompatibility testing were also performed. The data analyzed from the various tests substantiate that SonicFill 2 is as safe and effective as the predicate Metamorphosis (K091023). The following standards were utilized for the non-clinical performance testing of SonicFill 2:

- Guidance for Industry and FDA Staff: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions, November 27, 1998
- ISO 10993-1: 2009 Biological evaluation of medical devices
- ISO 10993-3:2003 Biological Evaluation of Medical Devices- Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-6:2007 Biological Evaluation of Medical Devices- Part 6: Tests for Local Effects after Implantation
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization
- ISO 14971:2007 Risk Management
- ISO 4049:2009 Dentistry- Polymer based Filling, Restorative, and Luting Materials.

Table 5.1: Predicate and Proposed Device Comparison Table

Element	Predicate Device- Metamorphosis	SonicFill 2
510(k)	Metamorphosis (K091023)	To be assigned
Trade Name	SonicFill, Sonic-Activated Bulk Fill Composite	SonicFill 2, Sonic-Activated Bulk Fill Composite
Target Users	Licensed dental professionals	Licensed dental professionals
Device Description	Metamorphosis, a nano-hybrid composite, is a light-cured, resin-based, dental restorative designed for direct placement. Metamorphosis is packaged into tips, which are custom-designed, single-dose and made from plastic. The single-dose tips are dispensed using the SonicFill 2010 Handpiece (K091091).	SonicFill2, a nano-hybrid composite, is a light cured, resin-based dental restorative designed for direct placement. SonicFill 2 uses the same delivery system as the predicate device Metamorphosis, which are custom-designed, single dose and made from plastic. The single-dose tips are dispensed using the same SonicFill 2010 Handpiece (K091091) as the predicate device.
Common Name	Dental Composite Restorative Material	Dental Composite Restorative Material
Classification Name	Tooth Shade Resin Material, per CFR § 872.3690 and Pit and Fissure Sealant and Conditioner, per CFR § 872.3765	Tooth Shade Resin Material, per CFR § 872.3690
Class	II	II
Product Code	EBF/ EBC	EBF/ EBC
Storage	Ambient Temperature	Ambient Temperature
Curing Mechanism	Photo initiation	Photo initiation
Material Compatibility	Biocompatibility meets requirements	Biocompatibility meets requirements
Shelf Life	24 months based on real time data	24 months based on accelerated data
UV Color Stability per ISO 4049	Pass	Pass
Volumetric Shrinkage	Pass	Equivalent to Predicate
Shrinkage Stress	Pass	Equivalent to Predicate
Depth of Cure	Pass	Pass
Light Sensitivity per ISO 4049	Pass	Pass
Flexural Strength per ISO 4049	Pass	Pass
Radiopacity per ISO 4049	Pass	Pass
Translucency	Pass	Pass
Working Time	Pass	Pass
Water Sorption/ Solubility per ISO 4049	Pass	Pass
Polishability	N/A	Pass

Clinical Performance Data

Clinical performance testing has not been performed for SonicFill 2.

Conclusion as to Substantial Equivalence

SonicFill 2 has been tested for its strength, depth of cure, shrinkage, polishability, color stability, and safety. It also has been verified as being substantially equivalent in performance, safety, and effectiveness to the predicate Metamorphosis (K091023).