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

Kerr Corporation
% Mohammad Ansari
Regulatory Affairs Specialist
Sybron Dental Specialties
1717 W. Collins Ave
Orange, California 92867

November 7, 2016

Re: K162257
Trade/Device Name: P1145 Dental Restorative
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: August 5, 2016
Received: August 11, 2016

Dear Mohammad Ansari:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Susan Runner DDS, MA

Tina Kiang, Ph.D.
Acting 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)*
(Not yet assigned)

Device Name

P1145 Dental Restorative

Indications for Use *(Describe)*
P1145, a nanohybrid dental restorative, is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include: repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups, 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.

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510(k) SUMMARY for P1145 Dental Restorative

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

1. Submitter Information**:**

Sybron Dental Specialties
1717 W. Collins Ave.
Orange CA, 92867

Contact Person: Wendy Garman
Telephone Number: 909-962-5666
Fax Number: 909-962-5694

Date Prepared: November 7, 2016

2. Device Name:

- Proprietary Name: P1145 Dental Restorative
- Classification Name: Tooth Shade Resin Material
- CFR Number: 872.3690
- Device Class: 2
- Product Code: EBF

3. Predicate Device:

The P1145 product line is substantially equivalent to the legally marketed device Herculite Ultra (K082671) cleared on December 11, 2008, product code EBF.

4. Description of Device:

P1145 is a light-cured, esthetic, resin-based nanohybrid dental restorative designed for direct placement in both anterior and posterior restorations. It is designed to be used after placement of a dental adhesive. Once placed, the composite can be easily sculpted to the desired shape, and after curing, can easily be finished and polished to achieve a highly esthetic restoration.

5. Indications for Use:

P1145, a nanohybrid dental restorative, is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include: repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups, core build-ups and incisal abrasions.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The technological characteristics of P1145 are virtually identical to those of the predicate device, Herculite Ultra (K082671). Both formulas mostly contain solid filler-particles, mixed with a resin system, in order to form a high viscosity paste which can be directly applied into a restoration preparation.

The filler systems in predicate Herculite Ultra (K082671) and P1145 are formulated in order to provide the composites its mechanical strength and durability, while maintaining excellent handling and esthetic characteristics. Additionally, the composites are formulated with methacrylate-based resin systems in combination with a photo-initiation system, which results in a polymerization of the composite when irradiated using a dental curing light.

Non-Clinical Performance Data

Non-clinical performance data included testing for mechanical strength (flexural strength, compressive strength, diametral tensile strength, Rockwell hardness), polishability, water sorption and solubility, depth of cure, light sensitivity, radiopacity, volumetric shrinkage, and color stability. Working time and gloss were also performed. The data analyzed from the various tests substantiate that P1145 is safe and effective as the predicate Herculite Ultra (K082671).

The following standards were utilized for non-clinical performance testing of P1145:

- 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 10993-11:2011 Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity
- 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 Herculite Ultra	Proposed P1145
510(k)	K121824	To be assigned
Trade Name	Herculite Ultra	P1145
Target Users	Licensed dental professionals	Licensed dental professionals
Device Description	Herculite Ultra is a light-cured, esthetic, resin-based dental restorative.	P1145 is a light-cured, esthetic, resin-based nanohybrid dental restorative designed for direct placement in both anterior and posterior restorations. It is designed to be used after placement of a dental adhesive. Once placed, the composite can be easily sculpted to the desired shape, and after curing, can easily be finished and polished to achieve a highly esthetic restoration.
Intended Use	Dental Restorative	Dental Restorative
Common Name	Dental Composite Restorative Material	Dental Composite Restorative Material
Classification Name	Tooth Shade Resin Material	Tooth Shade Resin Material
Class	2	2
Product Code	EBF	EBF
Storage	Store at room temperature.	Store at room temperature.
Indications for Use	Herculite Ultra is a dental composite restorative material intended to be used in all classes of cavities.	P1145, a nanohybrid dental restorative, is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include: repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups, core build-ups and incisal abrasions.
Curing Mechanism	Photo-initiation	Photo-initiation
Material Compatibility	Meets Biocompatibility Requirements	Meets Biocompatibility Requirements
Shelf Life	Minimum 36 months based on real time data	Minimum 24 months based on accelerated data
Particle Size Distribution	Nanohybrid: Proprietary formulation of nano and non-nano particle sizes of filler	Nanohybrid: Same

Clinical Performance Data

Clinical performance testing has not been performed for P1145.

Conclusion as to Substantial Equivalence

The technological characteristics of P1145 are virtually identical to the predicate Herculite Ultra (K082671). These proposed P1145 has similarities in select performance characteristics as compared to the predicate. The proposed P1145 is substantially equivalent to the predicate Herculite Ultra (K082671) based on the similarities in the two products in design, device performance, biocompatibility testing, and the same intended use. The proposed product P1145 and Herculite Ultra (K082671) have the same intended use and are to be used in dental restorative procedures. The proposed device P1145 has more specific indications, as compared to Herculite Ultra (K082671), to clearly define and describe the device applications and types of restorative procedures as well as describe the nanohybrid filler composition. Any noted differences in technological characteristics between the proposed and predicate products do not raise new questions of safety and effectiveness and demonstrate the proposed product is at least as safe and effective as the legally marketed predicate device. Both Herculite Ultra (K082671) and P1145 utilize a nanohybrid filler system and a similar methacrylate-based resin system to achieve the same function. Herculite Ultra (K082671) and P1145. Based on this reasoning and the results of ISO 4049:2009 performance testing, including mechanical strength, depth of cure, shrinkage, polishability, color stability, and biocompatibility testing, P1145 is substantially equivalent to the predicate Herculite Ultra (K082671).