Kerr Corporation
% Ardrena Jackson
Senior Regulatory Affairs Specialist
Sybron Dental Specialties
1717 W. Collins Ave
Orange, California 92867

November 7, 2018

Re: K182162
Trade/Device Name: OptiBond eXTRa Universal
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: August 8, 2018
Received: August 10, 2018

Dear Ardrena Jackson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.07 12:56:12 -05'00'

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182162

Device Name
OptiBond eXTRa Universal

Indications for Use *(Describe)*

Direct Bonding Applications

- Light-cured composite and compomer restorations.
- Composite/ceramic/metal repairs.
- Cavity sealing for amalgam restorations.
- Sealing of hypersensitive and/or exposed root surfaces.
- Core build-ups (self-cured, light-cured, or dual-cured).

Indirect Bonding Applications

- Veneers.
- Self-cure, dual-cure, light-cure resin cements and core buildup materials.
- Porcelain, ceramic (including zirconia-based, lithium disilicate-based and alumina-based), composite, and metal-based (including precious and non-precious metal inlays, onlays, crowns, bridges.
- Endodontic posts.
- Cavity sealing as a pretreatment for indirect restorations.

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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510K K182162

Sybron Dental Specialties

OptiBond eXTRa Universal

1. Submitter Information:

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

Contact Person: Ardrena Jackson
Telephone Number: 714-516-7491
Fax Number: 909-962-5694
Date Prepared: August 8, 2018

2. Device Name:

Classification Name	Resin tooth bonding agent
FDA CDRH Panel	Dental
Product Code	KLE
Regulation Number	872.3200
Class #	II

3. Predicate Device:
OptiBond XTR (K101423)

4. Description of Device:
OptiBond eXTRa Universal is a two-component universal adhesive system including a PRIMER and an ADHESIVE. The OptiBond eXTRa Universal PRIMER provides effective etching to enamel and dentin without the need for a separate phosphoric acid etch, thus simplifying the bonding procedure (self-etch technique). OptiBond eXTRa Universal is compatible with total etch and selective etch techniques. The OptiBond eXTRa Universal ADHESIVE is 15% filled with 0.4 micron barium glass to help reinforce bond strength.

5. Indications for Use:

Direct Bonding Applications

- Light-cured composite and compomer restorations.
- Composite/ceramic/metal repairs.
- Cavity sealing for amalgam restorations.
- Sealing of hypersensitive and/or exposed root surfaces.
- Core build-ups (self-cured, light-cured, or dual-cured).

Indirect Bonding Applications

- Veneers.
- Self-cure, dual-cure, light-cure resin cements and core buildup materials.
- Porcelain, ceramic (including zirconia-based, lithium disilicate-based and alumina-based), composite, and metal-based (including precious and non-precious metal inlays, onlays, crowns, bridges.
- Endodontic posts.
- Cavity sealing as a pretreatment for indirect restorations.

6. Summary of Non-Clinical Performance Data:

The technological characteristics of subject device OptiBond eXTRa Universal is substantially equivalent to the predicate OptiBond XTR (K101423). Bench testing was conducted on a variety of self-cure or dual-cure resin cements and core-build up materials. The following performance tests were completed during the product lifecycle:

Non-clinical performance data includes testing for shear bond strength to various substrates. The data analyzed from the various tests substantiate that OptiBond eXTRa Universal performs similar to the predicate OptiBond XTR (K101423). The following standards were utilized for non-clinical performance testing of OptiBond eXTRa Universal :

- 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 29022:2013* Dentistry – Adhesive-Notched Edge Sheer Bond Strength TestTesting of Adhesion to Tooth Structure

7. Summary of Technological Characteristics and Device Comparison:

The proposed OptiBond eXTRa Universal has similarities in performance characteristics and design features as compared to the predicate. The nonclinical performance testing demonstrates that the OptiBond eXTRa Universal performs as well as the predicate device OptiBond XTR (K101423). OptiBond eXTRa Universal has been tested for its shear bond strength against a variety of materials (including enamel, dentin, and common substrates) in all etching modes. Additional conformational biocompatibility testing was performed on the proposed OptiBond eXTRa Universal. The first difference in technological characteristics between the two devices is the replacement of one of the monomers in the formulation to another monomer that has the same function. The other difference in technological characteristics is the difference in techniques that the devices are marketed for. While predicate OptiBond XTR is for self-etch techniques, OptiBond eXTRa Universal can also be used in total and selective etch techniques. These technological differences were evaluated by testing the in-vitro shear bond strength of OptiBond eXTRa Universal using all etching techniques and comparing the performance in all modes to the predicate OptiBond XTR. The performance of OptiBond eXTRa Universal in any mode is statistically equivalent to predicate device OptiBond XTR in self-etch mode and does not raise concerns of safety and effectiveness. The differences in the formulation and the differences in application techniques do not raise concerns of safety and effectiveness. and demonstrate the subject device is at least as safe and effective as the legally marketed predicate device.

Element	Predicate OptiBond XTR	Subject Device OptiBond eXTRa Universal
510(k)	K101423	K182162
Manufacturer	Kerr Corporation	Kerr Corporation
Trade Name	OptiBond XTR	OptiBond eXTRa Universal
Target Users	Licensed Dental Professionals	Licensed Dental Professionals
Common Name	Bonding Agent	Same
Classification Name	Resin Tooth Bonding Agent	Same
FDA Class	II, 21 CFR 872.3200	Same
Product Code	KLE	Same
Device Description	OptiBond XTR is a two-component self-etch universal adhesive system including a self-etch PRIMER and a universal ADHESIVE. The self-etch primer provides effective etching to uncut enamel and dentin, without the need for a separate phosphoric acid etch, thus simplifying the bonding procedure. The adhesive component is 15% filled with 0.4	OptiBond eXTRa Universal is a two-component universal adhesive system including a self-etch PRIMER and a universal ADHESIVE. The OptiBond eXTRa Universal PRIMER provides effective etching to enamel and dentin without the need for a separate phosphoric acid etch, thus simplifying the bonding procedure (self-etch technique). OptiBond

Element	Predicate OptiBond XTR	Subject Device OptiBond eXTRa Universal
	micron barium glass to help reinforce bond strength. The material's chemistry allows for compatibility with all self-cure or dual-cure resin cements and core build-up materials. Dentists can therefore utilize OptiBond XTR for their direct procedures without the need for a secondary bonding system.	eXTRa Universal is compatible with total etch and selective etch techniques. The OptiBond eXTRa Universal ADHESIVE is 15% filled with 0.4 micron barium glass to help reinforce bond strength. The material's chemistry allows for compatibility with all self-cure or dual-cure resin cements and core build-up materials. Dentists can therefore utilize OptiBond eXTRa Universal for their direct and indirect procedures without the need for a secondary bonding system.
Intended Use	Resin tooth bonding agent used in direct and indirect bonding applications	Resin tooth bonding agent used in direct and indirect bonding applications
Indications for Use	OptiBond XTR is a two-component self-etch universal adhesive system designed to be used for all direct and indirect applications including, but not limited to, the following: Direct Applications • Light-cured composite and compomer restorations • Composite/ceramic/metal repairs • Cavity sealing for amalgam restorations • Sealing of hypersensitive and/or exposed root surfaces • Core build-ups (self-cured, light-cured or dual-cured) Indirect applications • Veneers • Porcelain, composite, and metal-based (including zirconia-based and alumina-based) inlays, onlays, crowns, bridges • Endodontic posts • Cavity sealing as a pretreatment for indirect restorations	**Direct Bonding Applications** • Light-cured composite and compomer restorations. • Composite/ceramic/metal repairs. • Cavity sealing for amalgam restorations. • Sealing of hypersensitive and/or exposed root surfaces. • Core build-ups (self-cured, light-cured, or dual-cured). **Indirect Bonding Applications** • Veneers. • Self-cure, dual-cure, light-cure resin cements and core buildup materials. • Porcelain, ceramic (including zirconia-based, lithium disilicate-based and alumina-based), composite, and metal-based (including precious and non-precious metal inlays, onlays, crowns, bridges. • Endodontic posts. • Cavity sealing as a pretreatment for indirect restorations.

Element	Predicate OptiBond XTR	Subject Device OptiBond eXTRa Universal
Principles of Operation	Primer is applied to tooth structure to etch and prepare the surface, then adhesive is applied facilitating adhesion to the restoration through micro-mechanical interlocking and chemical bonding	Same
Curing Mechanism	Photo-initiation	Same
Bonding Agent Type	2 component system (primer and adhesive)	Same
Technique	Self Etch	Self-etch, Total-etch, Selective-etch
Resin Type	methacrylate, GPDM	Same
Cure Time	Optilux 501 - 10 seconds L.E.Demetron I - 10 seconds L.E.Demetron II - 5 seconds Demi/Demi Plus/Demi Ultra - 5 seconds For all other lights see manufacturer's recommendation.	Same
Substrate Material Compatibility	Dentin, enamel, composite, ceramic, metal, amalgam	Same
Biocompatibility	Biocompatible per ISO 10993	Same
Storage conditions	Refrigerate upon receipt, between 2° - 8°C	Same
Shelf Life	2 years	Same
Accessories	Mixing well, applicator brushes	Same
Packaging Type (Delivery System)	Bottle, Unidose (nonsterile)	Same

8. Clinical Performance Data:
The company did not conduct clinical performance testing for OptiBond eXTRa Universal.

9. Conclusion as to Substantial Equivalence:
Based on technology, intended use, biocompatibility testing and non-clinical performance testing, the subject device OptiBond eXTRa Universal (K182162) is substantially equivalent to the predicate device OptiBond XTR (K101423).