Dentsply Sirona
Karl Nittinger
Director, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

September 28, 2018

Re: K181476
Trade/Device Name: Prime&Bond active Universal Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE
Dated: June 29, 2018
Received: July 2, 2018

Dear Karl Nittinger:

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

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)*

K181476

Device Name
Prime&Bond active™ Universal Adhesive

Indications for Use *(Describe)*

- Direct, light cured composite and compomer restorations.
- Light cured resin cemented veneers.
- Composite, ceramic and amalgam repairs.
- Cavity varnish for use with fresh amalgam.
- Indirect restorations and endodontic posts cemented with Calibra® Ceram.
- Desensitization of exposed dentin.
- Surface treatment of zirconia, metal, and composite.

In combination with DENTSPLY Self Cure Activator:
- Direct dual cure / self-cure composite restorations and core build-ups.
- Cementation of indirect restorations and endodontic posts using dual cure / self-cure resin cements.

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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SECTION 5. 510(k) SUMMARY
for
Prime&Bond active™ Universal Adhesive

1. Submitter Information:
   Dentsply Sirona
   221 West Philadelphia Street
   Suite 60W
   York, PA 17401

   Contact Person: Karl Nittinger
   Telephone Number: 717-849-4424
   Fax Number: 717-849-4343

   Date Prepared: 04 June 2018

2. Device Name:
   - Proprietary Name: Prime&Bond active™ Universal Adhesive
   - Classification Name: Resin Tooth Bonding Agent
   - CFR Number: 872.3200
   - Device Class: II
   - Product Code: KLE

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
Adhesive EXL 759 (Currently marketed as Scotchbond™ Universal)	K110302	3M Espe AG

Reference Device:

Reference Device Name	510(k)	Company Name
Calibra Ceram	K040906	Dentsply Sirona (formerly Dentsply International Inc.)
DENTSPLY Self Cure Activator	K964525	Dentsply Sirona (formerly Dentsply International Inc.)

4. Description of Device:

Prime&Bond active™ Universal Adhesive is a (meth) acrylate-based material which functions as a combined etch-and-rinse (Total-Etch), self-etch and selective-etch dental adhesive. It offers a simple adhesive application technique for both direct and indirect indications and bonds to enamel, dentin, composites, zirconia, and metals.

When used with DENTSPLY Self Cure Activator, Prime&Bond active™ Universal Adhesive is compatible with dual cure / self-cure resin cements, composites and core build-up materials.

Prime&Bond active™ universal adhesive offers operators the choice of enamel and dentin pre-treatment:

- Self-etch mode: no phosphoric acid etching prior to application
- Selective enamel-etch mode: selective phosphoric acid etching of enamel
- Etch-and-rinse mode: phosphoric acid etching of both enamel and dentin

5. Indications for Use:

- Direct, light cured composite and compomer restorations.
- Light cured resin cemented veneers.
- Composite, ceramic and amalgam repairs.
- Cavity varnish for use with fresh amalgam.
- Indirect restorations and endodontic posts cemented with Calibra® Ceram.
- Desensitization of exposed dentin.
- Surface treatment of zirconia, metal, and composite.

In combination with DENTSPLY Self Cure Activator:

- Direct dual cure / self-cure composite restorations and core build-ups.
- Cementation of indirect restorations and endodontic posts using dual cure / self-cure resin cements.

6. Substantial Equivalence:

Technological Characteristics:

Proposed Device **Prime&Bond active™ Universal Adhesive**	**Predicate Device** **Adhesive EXL 759 K110302**	**Differences**
Indications for Use:	**Indications for Use:**	
Direct light cured composite and compomer restorations	All classes of fillings (according to Black) with light-curing composite or compomer filling materials	No differences – classes of filling according to Black include direct restorations
Indirect restorations and endodontic posts cemented with Calibra Ceram	Cementation of indirect restorations (inlay, onlay, crowns, bridges, veneers) of composite, compomer, ceramic, and metal when combined with Suglue-10 Adhesive Resin Cement, manufactured by 3M ESPE	No differences– this indication describes the compatibility of the dental adhesive (proposed and predicate device) with a specific luting cement used for cementation of materials within indirect restoration or endodontic procedures. The adhesive bonds the cement to tooth substrates, the cement is the luting material for the indirect/endodontic application (depending on the indications for the cement). Calibra Ceram is the assigned (reference) cement for the proposed device, Suglue-10 Adhesive Resin Cement is the respective assigned (reference) cement for the predicate device
Light cured resin cemented veneers	Cementation of veneers when combined with RelyX Veneer Cement, manufactured by 3M ESPE	No differences– RelyX Veneer Cement is a typical resin based cement
	Bonding of core build-ups made of light-curing composite or core build-up materials.	No differences– for the proposed device this indication is included in "Direct light cured composite and compomer restorations"
Composite, ceramic and amalgam repairs	Repair of composite or compomer fillings Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer	No differences– repair of porcelain fused to metal includes bonding to metal surfaces, which is similar to amalgam bonding/repair.
Desensitization of exposed dentin	Root surface desensitization	No differences
Cavity varnish for use with fresh amalgam	Sealing of cavities prior to cementation of amalgamate restorations	No differences– Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect

Proposed Device **Prime&Bond active™ Universal Adhesive**	**Predicate Device** **Adhesive EXL 759 K110302**	**Differences**
	Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations.	restorations is not a proposed indication for the subject Prime&Bond active™ Universal Adhesive device.
	Bonding of fissure sealants	Minor indication, it is not a proposed indication for the subject Prime&Bond active™ Universal Adhesive device.
	Protective varnish for glass ionomer fillings	Minor indication, it is not a proposed indication for the subject Prime&Bond active™ Universal Adhesive device.
Surface treatment of zirconia, metal, and composite	Surface treatment of porcelain, ceramics (including glass ceramics, zirconia and alumina), metal and composite.	No differences – treatment of glass ceramics and alumina is not a proposed indication for the subject Prime&Bond active™ Universal Adhesive device.
In combination with DENTSPLY Self-cure Activator : • Direct dual-cure/ self-cure composite restorations and core build-ups	Bonding of dual-cure cements and core build-up materials and self-cure composites when combined with Activator EXL 760	No differences – split into two indications for the proposed device. The term “dual-cure” includes “self-cure” mode.
• Cementation of indirect restorations and endodontic posts using dual cure/self-cure resin cements.		
Features:	**Features:**	**Differences:**
One-component, light-curing universal dental adhesive	Single-component, light curing adhesive	No differences
Self-etch, selective enamel-etch mode, or etch-and rinse mode; light curing of adhesive	Self-etch, selective enamel-etch mode, or etch-and-rinse mode; light curing of adhesive	No differences
• Light-curing universal adhesive used with Self-cure Activator; traditional resin cement • Light-curing universal adhesive used without Self-cure Activator for assigned (reference) cement	• Light-curing universal adhesive used with separate Activator; traditional resin cement • Light-curing universal adhesive used without separate Activator for assigned (reference) cement	No differences

7. Non-Clinical Performance Data:

   The following in vitro bench tests were performed on the Prime&Bond active™ Universal Adhesive to verify physical properties and performance in support of substantial equivalence:

   - pH measurement according to internal method.
   - Density measurement according to internal method.
   - Film thickness measurement according to internal method.
   - Shear Bond Strength on enamel and dentin according to ISO 29022 “Dentistry – Adhesion – Notched edge shear bond strength test” (direct restorations).
   - Shear Bond Strength on enamel and dentin (indirect restorations) according to internal test method.
   - Shear Bond Strength on Zirconia Ceramic, Base Metal, Noble Metal, and Composite (indirect restorations) according to internal test method.

   The performance of the Prime&Bond active™ Universal Adhesive satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

   A cytotoxicity test was performed for the Prime&Bond active™ Universal Adhesive as well as chemical analysis of leachable organic and inorganic compounds in compliance with the standard EN ISO 10993-1. The results of the biocompatibility testing and chemical analysis conducted relating to the subject Prime&Bond active™ Universal Adhesive support its substantial equivalence.

8. Clinical Performance Data.

   No data from human clinical studies has been included to support the substantial equivalence of the Prime&Bond active™ Universal Adhesive.

9. Conclusion Regarding Substantial Equivalence

   The Prime&Bond active™ Universal Adhesive is a dental adhesive which is intended to bond resin-based materials to enamel and dentin as well as to metal and ceramic. The Prime&Bond active™ Universal Adhesive has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate Adhesive EXL 759 cleared under premarket notification K110302. Test data to verify physical properties and the performance of the Prime&Bond active™ Universal Adhesive has been provided including: appearance, pH, density, film thickness, Shear Bond Strength on various substrates. The results of this testing, combined with the design and intended use comparison with the predicate device Adhesive EXL 759 (K110302), support substantial equivalence.