



Food and Drug Administration
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October 30, 2015

DENTSPLY International Inc.
Ms. Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, PA 17401

Re: K151619

Trade/Device Name: Prime&Bond Elect[®] Universal Dental Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: II
Product Code: KLE
Dated: August 03, 2015
Received: August 04, 2015

Dear Ms. Lewis:

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" (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 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 yours,

 Tina
Kiang -S

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

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K151619

Device Name: Prime&Bond Elect® Universal Dental Adhesive

Indications for Use:

1. Prime&Bond Elect® Universal Dental Adhesive (visible light cured):
 - 1.1 Direct, light cured composite and compomer restorations
 - 1.2 Indirect restorations; light cured, resin cemented veneers
 - 1.3 Indirect restorations; acid-tolerant resin cement (dual cure or self-cure) cemented inlays, onlays, crown and bridge retainers
 - 1.4 Composite, ceramic and amalgam repairs
 - 1.5 Cavity varnish for use with fresh amalgam
2. Prime&Bond Elect® Universal Dental Adhesive mixed with Self-Cure Activator (dual cure or self-cure):
 - 2.1 Direct, dual cure or self-cure composite restorations and core build-ups
 - 2.2 Indirect restorations; dual cured and self-cured resin cemented inlays, onlays, crown and bridge retainers
 - 2.3 Dual cured and self-cured resin cemented endodontic post cementation
3. Prime&Bond Elect® Universal Dental Adhesive mixed with Self-Cure Activator and Amalgam Bonding Base & Catalyst:
 - 3.1 Adhesive bonding of direct amalgam restoration
4. Prime&Bond Elect® Universal Dental Adhesive (without Self-Cure Activator or adhesive curing):
 - 4.1 Indirect restorations; acid-tolerant resin cement light-cured cementation; light transmissible inlays, onlays, crown and bridge retainers with light curing of cement
 - 4.2 Indirect restorations; acid-tolerant resin cement dual cure or self-cure cementation; limited light/light opaque inlays, onlays, crown and bridge retainers and endodontic posts with total etch technique

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5. 510(k) SUMMARY

DENTSPLY

for
Prime&Bond Elect® Universal Dental Adhesive

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
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York, PA 17401
(800) 877-0020
Fax (717) 849-4343
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1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17401

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 12 June 2015

2. Device Name:

- Proprietary Name: Prime&Bond Elect® Universal Dental Adhesive
- Classification Name: Resin tooth bonding agent
- CFR Number: 872.3200
- Device Class: Class II
- Product Code: KLE

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
XENO® Adhesive with Activator	K051463	DENTSPLY International Inc.

4. Description of Device:

Prime&Bond Elect® Universal Dental Adhesive is a universal self-priming dental adhesive system designed to bond resin based materials to enamel and dentin as well as to metals and ceramic. Prime&Bond Elect® Universal Dental Adhesive combines etchant, primer and adhesive in a one-bottle material. This robust formulation allows the operator to utilize selective phosphoric acid etching of enamel, phosphoric acid etching of both enamel and dentin, or no phosphoric acid etching prior to application, ensuring high bond strength and protection against microleakage.

When mixed with Self-Cure Activator, Prime&Bond Elect® Universal Dental Adhesive is designed to be used with DENTSPLY manufactured dual cure/self-cure resin cements* to bond all indirect restorations and DENTSPLY manufactured dual cured composite restoratives. When used with the Amalgam Bonding Accessory Kit, available separately, Prime&Bond Elect® Universal Dental Adhesive also adhesively bonds fresh amalgam to enamel and dentin.

*Note: Acid-tolerant resin cements may be used following application of Prime&Bond Elect® adhesive without the use of Self-Cure Activator, additionally allowing operator's choice of pre-cementation adhesive curing options (see complete Directions for Use).

1. Indications for Use:

1. Prime&Bond Elect® Universal Dental Adhesive (visible light cured):
 - 1.1 Direct, light cured composite and compomer restorations
 - 1.2 Indirect restorations; light cured, resin cemented veneers
 - 1.3 Indirect restorations; acid-tolerant resin cement (dual cure or self-cure) cemented inlays, onlays, crown and bridge retainers
 - 1.4 Composite, ceramic and amalgam repairs
 - 1.5 Cavity varnish for use with fresh amalgam
2. Prime&Bond Elect® Universal Dental Adhesive mixed with Self-Cure Activator (dual cure or self-cure):
 - 2.1 Direct, dual cure or self-cure composite restorations and core build-ups
 - 2.2 Indirect restorations; dual cured and self-cured resin cemented inlays, onlays, crown and bridge retainers
 - 2.3 Dual cured and self-cured resin cemented endodontic post cementation
3. Prime&Bond Elect® Universal Dental Adhesive mixed with Self-Cure Activator and Amalgam Bonding Base & Catalyst:
 - 1.1 Adhesive bonding of direct amalgam restoration
4. Prime&Bond Elect® Universal Dental Adhesive (without Self-Cure Activator or adhesive curing):
 - 4.1 Indirect restorations; acid-tolerant resin cement light-cured cementation; light transmissible inlays, onlays, crown and bridge retainers with light curing of cement
 - 4.2 Indirect restorations; acid-tolerant resin cement dual cure or self-cure cementation; limited light/light opaque inlays, onlays, crown and bridge retainers and endodontic posts with total etch technique

6. Substantial Equivalence:

All of the components found in proposed Prime&Bond Elect® Universal Dental Adhesive have been used in legally marketed devices.

The proposed device, Prime&Bond Elect® Universal Dental Adhesive, includes light curing Prime&Bond Elect® Universal Dental Adhesive and separate Self-Cure Activator (SCA). The predicate device, XENO® Adhesive with Activator (K051463), includes light curing Xeno® Adhesive and separate Self-Cure Activator (SCA). The light curing adhesive formulation of Prime&Bond Elect® Universal Dental Adhesive is identical to light curing portion of the predicate XENO® Adhesive with Activator (K051463). When used for direct applications, Prime&Bond Elect® Universal Dental Adhesive in self-etch mode is exactly the same as light curing portion of the predicate XENO® Adhesive with Activator (K051463).

Prime&Bond Elect® Universal Dental Adhesive allows the operator to utilize selective phosphoric acid etching of enamel, phosphoric acid etching of both enamel and dentin, or no phosphoric acid etching prior to application. XENO® Adhesive with Activator (K051463) has been marketed as a self-etch adhesive only, without the option of phosphoric acid conditioning.

This technique modification allowing utilization of phosphoric acid conditioning prior to adhesive application is new in comparison to the predicate device, XENO® Adhesive with Activator (K051463).

When used for indirect applications in combination with traditional resin cements, which are not compatible with most one-bottle light curing adhesives, Prime&Bond Elect® Universal Dental Adhesive should be coupled with the same Self-Cure Activator, in exactly the same way as XENO® Adhesive with Activator (K051463).

When Prime&Bond Elect® Universal Dental Adhesive is used with an acid tolerant resin cement, no separate Self-Cure Activator is needed if:

- The adhesive is applied in self-etch, selective enamel etch, or total (enamel and dentin) etch technique and light cured prior to application of acid tolerant resin cement, all types of indirect restorations
- The adhesive is applied in self-etch, selective enamel etch, or total (enamel and dentin) etch technique without light curing; light curing of acid tolerant resin cement through light transmissible indirect restorations
- The adhesive is applied in total (enamel and dentin) etch technique without light curing; self-curing of acid tolerant resin cement through light opaque indirect restorations

The design and formulation is identical to the predicate device, XENO® Adhesive with Activator (K051463), and therefore the biocompatibility data and the performance data of the legally marketed of XENO® Adhesive with Activator (K051463) provided in premarket notification K051463 support the proposed device, Prime&Bond Elect® Universal Dental Adhesive, for the indicated uses.

Table 5.1 shows the similarities and differences of the indications for use for: XENO® Adhesive with Activator (K051463) as the predicate device, and proposed changes for Prime&Bond Elect® Universal Dental Adhesive.

Table 5.1 Similarities and Differences between the proposed and the predicate devices

Element	Predicate device	Proposed device
Product Name	XENO® Adhesive with Activator (K051463)	Prime&Bond Elect® Universal Dental Adhesive
Features	Light, Dual, Self-cured Dental Adhesive	Universal Dental Adhesive
	Adds Optional Self-Cure Activator for additional Dual Cure/Self-cure Compatibility Indications	<i>Identical Adhesive and Self-Cure Activator to K051463</i> Adds technique modification; selective etch capability Adds Indications for Adhesive use alone when used with acid tolerant cement; No Light Cure, No Self-Cure Activator
Indications for use		1. Prime&Bond Elect® Universal Dental Adhesive (visible light cured)
	Direct, light-cured composite and compomer restorations	1.1 Direct, light-cured composite and compomer restorations
	Indirect restorations; Light-cured resin cemented veneers	1.2 Indirect restorations; Light-cured resin cemented veneers
		1.3 Indirect restorations; acid tolerant resin cement (dual or self-cure) cemented inlays, onlays, crown and bridge retainers
	Composite, ceramic and amalgam repairs	1.4 Composite, ceramic and amalgam repairs
	Cavity Varnish for use with fresh amalgam	1.5 Cavity Varnish for use with fresh amalgam
		2. Prime&Bond Elect® Universal Dental Adhesive mixed with Self-Cure Activator (Dual Cure or Self-cure)
	Direct, dual-cure or self-cure composite restorations and core build-ups	2.1 Direct, dual-cure or self-cure composite restorations and core build-ups

Element	Predicate device	Proposed device
	Resin cemented inlays, onlays, crown and bridge retainers	2.2 Indirect restorations; dual cured and self-cured resin cemented inlays, onlays, crown and bridge retainers
	and endodontic post cementation;	2.3 Dual Cured and Self-cured resin cemented endodontic post cementation
		3. Prime&Bond Elect® Universal Dental Adhesive mixed with Self-Cure Activator and Amalgam Bonding Base & Catalyst)
	Adhesive bonding of direct amalgam restorations	3.1 Adhesive bonding of direct amalgam restorations
		4. Prime&Bond Elect® Universal Dental Adhesive (Self-cure without Self-Cure Activator or adhesive curing)
		4.1 Indirect restorations; acid-tolerant resin cement light-cured cementation; light transmissible inlays, onlays, crown and bridge retainers with light curing of cement
		4.2 Indirect restorations; acid-tolerant resin cement dual cure or self-cure cementation; limited light/light opaque inlays, onlays, crown and bridge retainers and endodontic posts with total etch technique
Component for direct	One-bottle light curing adhesive	One-bottle light curing adhesive
Technique for direct	Self-etch only; light curing of adhesive	Self-etch, selective enamel etch or total etch; light curing of adhesive

Element	Predicate device	Proposed device
Component for indirect	Light curing adhesive used with Self-Cure Activator; traditional resin cement	<ul style="list-style-type: none"> • Light curing adhesive used with Self-Cure Activator; traditional resin cement • One-bottle light curing adhesive without Self-Cure Activator; acid-tolerant resin cement
Technique for Indirect	Self-etch only. Light curing adhesive mixed with Self-Cure Activator (1:1)	<p>Self-etch, selective enamel etch or total etch:</p> <ul style="list-style-type: none"> • Light curing adhesive mixed with Self-Cure Activator (1:1) • One-bottle light curing adhesive; with acid-tolerant cement • One-bottle adhesive, no light curing; light cured acid tolerant cement, light transmissible restoration <p>Total etch:</p> <ul style="list-style-type: none"> • One-bottle adhesive, no light curing; self-cured acid tolerant cement, light opaque restoration

7. Non-Clinical Performance Data.

Biocompatibility Testing

The biocompatibility requirements for the proposed device, Prime&Bond Elect® Universal Dental Adhesive have not changed from the predicate device XENO® Adhesive with Activator (K051463). Therefore, no additional biocompatibility tests were performed as the proposed device is identical in design and formulation to the predicate device XENO® Adhesive with Activator (K051463).

Physical Properties

There are no changes affecting the fundamental technology and chemical composition of Prime&Bond Elect® Universal Dental Adhesive. The physical characteristics and mechanical properties of the material are not affected. Table 5.2 shows the testing performed on the proposed device and all of the test results have met the specifications.

Table 5.2- Physical Properties Tested	
Physical Property	Results
Film Thickness	Meets specification
Dentin Shear Bond Strength, Indirect	Meets specification
Enamel Shear Bond Strength, Indirect	Meets specification
Dentin Shear Bond Strength, Direct	Meets specification
Enamel Shear Bond Strength, Direct	Meets specification
Composite Bond Strength, Indirect	Meets specification
Base Metal Shear Bond Strength, Indirect	Meets specification
Noble Metal Shear Bond Strength, Indirect	Meets specification
Zirconia Ceramics Bond Strength, Indirect	Meets specification
Glass Ceramic Shear Bond Strength, Indirect	Meets specification
Shelf Life	2 Years

8. Clinical Performance Data. Clinical performance is not required for this 510(k) submission for there are no changes affecting the proposed device, Prime&Bond Elect® Universal Dental Adhesive.

9. Conclusion Regarding Substantial Equivalence

The Prime&Bond Elect® Universal Dental Adhesive is a self-priming dental adhesive which is intended to bond resin based materials to enamel and dentin as well as to metals and ceramic. The Prime&Bond Elect® Universal Dental Adhesive has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate XENO® Adhesive with Activator cleared under premarket notification K051463. Test data such as appearance, pH, Specific Gravity and Film Thickness to verify the performance of the Prime&Bond Elect® Universal Dental Adhesive have been provided. The results of this testing, combined with the design and intended use comparison with the predicate device, XENO® Adhesive with Activator (K051463), support substantial equivalence.