



Food and Drug Administration  
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September 18, 2015

Parkell, Inc.  
Mr. David Mott, Esq.  
VP, Regulatory Affairs  
300 Executive Drive  
Edgewood, New York 11717

Re: 151518  
Trade/Device Name: Brush & Bond<sup>®</sup> Plus  
Regulation Number: 21 CFR 872.3200  
Regulation Name: Resin tooth bonding agent  
Regulatory Class: II  
Product Code: KLE  
Dated: June 19, 2015  
Received: June 22, 2015

Dear Mr. Mott:

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

## Indications for Use

510(k) Number (if known)  
K151518

Device Name  
BRUSH&BOND® PLUS

Indications for Use (Describe)

BRUSH&BOND® PLUS is indicated for:

1. Direct Dental Restorations (e.g., resin-based composite, resin-modified glass ionomer, resin core build-ups, compomers).
2. Indirect Dental Restorations (e.g., metal, resin-based composite, dental ceramics (e.g., porcelain, pressed ceramic, lithium disilicate, zirconia).
3. Desensitization of dentin.
4. Sealing of dentin, cementum or enamel.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary

### 1. Submitter:

Parkell, Inc.  
 300 Executive Drive  
 Edgewood, NY 11717

### 2. Contact:

David Mott, Esq.  
 VP, Regulatory Affairs  
 Tel: (631) 249-1134, ext. 145  
 Fax: (631) 249-1242

### 3. Submission Date: June 4, 2015

### 4. Device Identification:

Trade Name: BRUSH&BOND® PLUS  
 Common Name: Dental Bonding Agent  
 Classification Name: Resin Tooth Bonding Agent (21CFR Section 872.3200)  
 Product Code: KLE  
 Classification: Class II

### 5. Predicate and Reference Devices:

Predicate Device: BRUSH&BOND® (510k no. 020239, filed as Touch&Bond-Pius)  
 Reference Device: All-Bond Universal® (510K no. 131734, filed as All-Bond Universal SC)

### 6. Description of Applicant Device:

BRUSH&BOND® PLUS is a self-etching, self-priming, light-cured bonding system which utilizes proven 4-META chemistry to enhance penetration into prepared enamel and dentin surfaces and to establish strong bonds to dental surfaces such as restorative composites, metals, dentin, enamel, cementum, and dental ceramics (e.g., porcelain, lithium disilicate, zirconia, or hybrid ceramics). The Device is useful for all direct and indirect dental restorations, desensitizing teeth, and sealing tooth structures against microleakage. Moreover, the Device can be used without prior acid-etching of dentin or cutting of enamel surfaces.

The BRUSH&BOND® PLUS device is essentially a single-bottle, two-component system, comprising: a liquid resin which comprises monomers and 4-META chemistry, and an activator brush which comprises a bonding promoter to ensure complete activation and polymerization when contacted with the liquid resin. After activation, the activated resin can be applied directly onto restorative surfaces (except dental ceramic surfaces) using the activator brush or any appropriate dental instrument. For ceramic surfaces, the surface must first be coated with a ceramic primer (such as EaZy Primer'M, 510K no. 142848) before the activated resin is applied.

BRUSH&BOND® PLUS is packaged as a single 3 mL bottle of liquid resin, an accompanying canister containing 100 activator brushes (either standard size or mini/endo size), and accompanying bottles of Parkell's ceramic primer Ea Primer'M (5mL "A" and "B" bottles).

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## 7. Intended Uses:

1. Direct dental restorations (e.g., resin-based composite, resin-modified glass ionomer, resin core build-ups, compomers).
2. Indirect dental restorations (e.g., metal, resin-based composite, dental ceramics (e.g., porcelain, pressed ceramic, lithium disilicate, zirconia)).
3. Desensitization of dentin.
4. Sealing of dentin, cementum or enamel.

## 8. Technological Characteristics:

BRUSH&BOND® PLUS is a single-bottle, dual-component bonding system, comprising: a liquid resin which comprises monomers and 4-META chemistry; and an activator brush which comprises a bonding promoter to ensure complete activation and polymerization when contact is made with the liquid resin. It is packaged as a single 3 mL bottle of liquid resin, an accompanying canister containing 100 activator brushes (either standard size or mini/endo size), and accompanying bottles of Parkell's ceramic primer, EaZy Primer 1<sup>M</sup>, 510K no. 142848 (5-millimeter "A" and "B" bottles).

All components of BRUSH&BOND® PLUS are found in legally marketed predicate devices. The BRUSH&BOND® PLUS is based upon industry standard monomer chemistry and has similar technological characteristics as other legally marketed bonding agents.

## 9. Biocompatibility:

An evaluation of biocompatibility was conducted to determine the safety of BRUSH&BOND® PLUS in accordance with ISO 10993-1: 2009, ISO 10993-5: 2009, ISO 10993-12: 2009, and the guidance document, "Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing". The biocompatibility evaluation included cytotoxicity testing in accordance with ISO 10993-5:2009, skin sensitization testing in accordance with ISO 10993-10:2010, and oral mucosa stimulation testing in accordance with ISO 10993-10:2010. The conclusion of the evaluation is that BRUSH&BOND® PLUS can be considered biocompatible.

## 10. Substantial Equivalence:

Information provided in this 510(k) submission demonstrates that BRUSH&BOND® PLUS is substantially equivalent to the Predicate Device, Parkell Inc.'s existing BRUSH&BOND® bonding agent (K020239) in terms of bond strength to dentin and enamel, as well as to the Reference Device (K131734) in terms of in terms of bond strength to metals, composite resin, and dental ceramics. The Shear and Tensile Bond Strength tests were performed in accordance with ISO/TS 11405. The shear and tensile strength tests were compared to the Predicates and were determined to be equivalent.

Any minor differences between the Device and the Predicate Device do not raise new questions of equivalence. Thus, this submission demonstrates the substantial equivalence of BRUSH&BOND® PLUS. A brief comparison of BRUSH&BOND® PLUS to the Predicate and Reference Devices is provided below:

Table 5-1:

Property (pass/fail criteria! if applicable)	BRUSH&BOND® PLUS (Parkell, Inc.)	Predicate Device (Brush&Bond®) (Parkell, Inc.)	Reference Device (All-Bond Universal®) (Bisco, Inc.)
Intended uses	<p>1. DirectDental Restorations (e.g. resin-based composite, resin-modified glass ionomer, resin core build-ups, compomers).</p> <p>2. Indirect Dental Restorations (e.g., metal, resin-based composite, dental ceramics, e.g., porcelain pressed ceramic, lithium disilicate, zirconia).</p> <p>3. Desensitization of dentin.</p> <p>4. Sealing of dentin, cementum or enamel.</p>	<p>1. A dentin bonding agent used with direct filling materials that include but may not be limited to, composite resins, resin modified glass ionomers or compomers, etc.</p> <p>2. A dentin bonding agent used with resin cements or composite luting agents to retain indirect tooth-colored and cast alloy restorations that include but may not be limited to indirect composite or porcelain inlays and onlays, laminate veneers, either resin or porcelain, porcelain-fused-to-metal crowns, etc.</p> <p>3. Treatment of hypersensitive areas of exposed root surfaces.</p> <p>4. A cavity sealant and desensitizer applied to exposed dentin that has been prepared to receive a laboratory fabricated restoration such as porcelain-fused-to-metal crowns, cast alloy or tooth-colored inlays, onlays veneers, etc.</p>	<p>1. Direct Restorations (e.g. resin-based composite, resin-modified glass ionomer, core build-ups)</p> <p>2. Indirect Restorations (e.g. metal, glass, ceramics, zirconia/alumina)</p> <p>3. Bonding Resin or Primer for Substrates</p> <p>4. Desensitization/Sealing of Tooth</p> <p>5. Intraoral Repair (e.g. chipped porcelain, additions to direct restorations)</p>
Classification Product Code	KLE	KLE	KLE
Self-Etching	Yes	Yes	Yes
Self-priming	Yes	Yes	Not available
Light-cured	Yes	Yes	Yes

Compatible with self dual, and light cured materials	Yes	Yes	Yes
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Table 5-1(continued):

Property {pass/fail criteria, if applicable}	<b>BRUSH&amp;BOND® PLUS (Parkell, Inc.)</b>	<b>Predicate Device (Brush&amp;Bond®) (Parkell, Inc )</b>	<b>Reference Device (All-Bond Universal®) (Sisco, Inc.)</b>
Shelf Life	3 years	3 years	2 years
Chemical components	Bonding agent, comprising a liquid resin which comprises monomers and 4-META chemistry; a ceramic primer; an activator brush comprising a bonding promoter.	Bonding agent, comprising a liquid resin which comprises monomers and 4-META chemistry; and an activator brush comprising a bonding promoter.	Bonding agent, comprising an ethanol/water-based dental adhesive; and a porcelain primer.

## 11. Clinical Performance Data

There was no clinical testing required to support the Device as the indications for use are equivalent to the Predicate Device. These types of devices, including the Predicate Device, have been on the market for many years with no reported adverse events. The non-clinical testing detailed in this submission supports the substantial equivalence of the Device.

## 12. Statement of Substantial Equivalence:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

The Device (BRUSH&BOND® PLUS) has the same or similar intended use, indications, principles of operation, and technological characteristics as the Predicate Device (BRUSH&BOND®). The Device, as designed and manufactured, is determined to be substantially equivalent to the Predicate Device in terms of intended use, design, materials, and function.