Parkell, Inc.
David Mott
VP, Regulatory Affairs; General Counsel
300 Executive Drive
Edgewood, New York 11717

November 21, 2017

Re: K172176
Trade/Device Name: Parkell Universal Adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: October 23, 2017
Received: October 24, 2017

Dear Mr. David 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.

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.

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 -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172176

Device Name
Parkell® Universal Adhesive

Indications for Use *(Describe)*

1. Direct dental restorations (e.g., resin-based composites, resin-modified glass ionomers, resin core build-ups, compomers).

2. Indirect dental restorations (e.g., metal, resin-based composite, dental ceramics such as porcelain, pressed ceramic, lithium disilicate, lithium silicate or 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K172176
510(k) Summary

1. Submitter:

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   Edgewood, NY 11717

2. Contact:

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   VP, Regulatory Affairs
   Tel: (631) 389-1545
   Fax: (631) 249-1242
   dmott@parkell.com

3. Submission Date: October 23, 2017

4. Device Identification:

Trade Name:	Parkell® Universal Adhesive
Common Name:	Dental Bonding Agent
Classification Name:	Resin Tooth Bonding Agent (21 CFR Section 872.3200)
Product Code:	KLE
Classification:	Class II

5. Predicate Device:

   Scotchbond® Universal Adhesive (K110302)/(3M ESPE)

6. Description of Proposed Device:

   The Parkell® Universal Adhesive is a single-component, one-bottle, light-cured universal bonding agent which utilizes proven 4-META and 10-MDP 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 Parkell® Universal Adhesive will be provided in a single bottle, with standard applicator brushes for applying the adhesive to treatment surfaces.

7. Intended Use:

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

   As so described and as demonstrated in Table 5-A, the Device has the same intended uses as the Predicate Device (Scotchbond™ Universal Adhesive, 510K no. 110302, which has been marketed since about 2011), in that both devices are useful for direct and indirect dental restorations *(e.g.,* inlays, onlays, crowns, bridges, varnishes and veneers), desensitizing

teeth and root surfaces, and sealing tooth structures and cavities. Any differences in the descriptions of intended uses of the Device and Predicate Device, to the extent that they exist, are minor, not critical to the intended therapeutic uses of the Device, and do not affect the safety and/or effectiveness of the Device when used as labeled.

8. Technological Characteristics:

The proposed device, Parkell® Universal Adhesive, has the same intended use and contains similar chemical components to that of the predicate device (Scotchbond™ Universal Adhesive, K110302). The proposed device and its predicate both contain several of the same chemical components as well as identical functional categories of components, with the exception of a "filler" which is included only in the Predicate Device. The differences in chemical composition across the Device and Predicate Device are believed to have insubstantial effects on the intended use of the Device. This is evidenced by substantially similar performance by the proposed device and predicate devices in performance tests on a variety of dental substrates, as described in the device comparison table below.

Most importantly, all chemical components found in the proposed Device, but not within the Predicate Device, are commonly-used chemicals that are present in many FDA-cleared dental products which have long histories of safe use.

9. Biocompatibility:

An evaluation of biocompatibility was conducted to determine the safety of Parkell® Universal Adhesive in accordance with ISO 10993-1: 2009, ISO 10993-3:2014, ISO 10993-5: 2009, ISO 10993-10:2010, ISO 10993-12: 2012, ISO 10993-33:2015, and the Final FDA Guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (June 16, 2016). The conclusion of the evaluation is that Parkell® Universal Adhesive can be considered biocompatible.

10. Substantial Equivalence[2]:

Information provided in this 510(k) submission demonstrates that Parkell® Universal Adhesive is substantially equivalent to the Predicate Device, 3M ESPE's Scotchbond® Universal Adhesive (K110302) in terms of bond strength to dentin, enamel,metals, composite resins, and dental ceramics. The shear bond strength tests were performed in accordance with ISO standards. The bond strengths achieved by the Device were compared to that of the Predicate Device and were determined to be equivalent.

Any differences between the Device and the Predicate Device, for purposes of this 510(k) submission, do not raise new questions of safety or effectiveness. Thus, this submission demonstrates the safety and effectiveness of Parkell® Universal Adhesive. A brief comparison of Parkell® Universal Adhesive to the Predicate Device is provided below:

[1] All statements contained herein are made solely for the purpose of demonstrating substantial equivalence as that term is defined in the context of SIO(k) submissions; the statements cannot be applied reliably or accurately in the context of U.S. patent or other intellectual property laws which involve vastly different legal standards and definitions (such as, *e.g.*, within the context of 35 U.S.C. §§ 102, 103, 112, 271).

[2] See FN 1.

Table 5-A:

	Parkell® Universal Adhesive (Parkell, Inc.)	**Predicate Device** (Scotchbond® Universal Adhesive) (3M)
	K172176	K110302
Intended use	1. Direct dental restorations (e.g., resin-based composites, resin-modified glass ionomers, resin core build-ups, compomers). 2. Indirect dental restorations (e.g., metal, resin-based composite, dental ceramics such as porcelain, pressed ceramic, lithium disilicate, lithium silicate or zirconia). 3. Desensitization of dentin. 4. Sealing of dentin, cementum or enamel.	1. All classes of fillings (according to Black) with composite or compomer. 2. Cementation of indirect restorations (crowns, inlays) of composite or compomer, ceramic and metal; Bonding of dual cure and chemical cure cements, core build-up materials and composites (with activator); Cementation of veneers; Intraoral repair of existing composite, porcelain fused to metal, and all ceramic restorations w/o extra primer; Bonding of core build-ups made of composite or core build-up materials; Repair of composite or compomer fillings 3. Root surface desensitization 4. Sealing of cavities prior to cementation of amalgam restorations; Sealing of cavities and preparations of tooth stumps prior to temporary cementation of indirect restorations 5. Protective varnish for glass ionomer fillings; 6. Bonding of pit and fissure sealants
Classification Product Code	KLE	KLE
Regulation Number	872.300	872.300
Self-Etching	Yes	Yes
Self-Priming	Yes	Yes
Light-Cured	Yes	Yes
Single bottle system	Yes	Yes
Compatible with Self-, Dual-, & Light-Cure Materials	Yes	Yes
Chemical components	Comprises several resins including 10-MDP.	Comprises several resins including 10-MDP.

Table 5-B:

Shear Bond Strength, Initial (MPa} Pass/fail criteria: at least about 6MPa ("<::6MPa")		**Parkell® Universal Adhesive** (Parkell, Inc.) K172176	**Predicate Device** (Scotchbond® Universal Adhesive) (3M) K110302
Enamel		<::6MPa	<::6MPa
Dentin		<::6MPa	<::6MPa
Silver alloy		<::6MPa	<::6MPa
Cobalt-chrome alloy		<::6MPa	<::6MPa
Porcelain, following acid etching		<::6MPa*	<::6MPa
Porcelain, following sandblasting		<::6MPa*	<::6MPa
Lithium disilicate, following sandblasting		<::6MPa*	<::6MPa
Lithium d1s111cate, followmg HF acid etching		<::6MPa*	<::6MPa
Zirconia, following sandblasting		<::6MPa	<::61vwa
Composite Resin	selt-cure	<::6MPa	<::bMPa
	11gnt-cure	<::bMPa	<::6MPa

* - pretreated with silane/ceramic 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 (Parkell® Universal Adhesive) has the same or similar intended use, indications, principles of operation, and technological characteristics as the Predicate Device (Scotchbond® Universal Adhesive). The Device, as designed and manufactured, is determined to be substantially equivalent to the Predicate Device in terms of intended use, design, and function.