January 20, 2022

Parkell, Inc
La-Shaunda Joseph
Regulatory/Compliance Manager
300 Executive Drive
Edgewood, New York 11717

Re: K210259
Trade/Device Name: Parkell Self-Adhesive Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: January 4, 2022
Received: January 6, 2022

Dear La-Shaunda Joseph:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K210259

Device Name
Parkell Self-Adhesive Cement

Indications for Use *(Describe)*

Parkell Self-Adhesive Cement is intended for the cementation of indirect restoratives including ceramic, zirconia, composite, and metal-based inlays, onlays, crowns, bridges, and posts.

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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510(k) Summary **K210259**

1. **Submitter**

Parkell, Inc.
300 Executive Drive
Edgewood, NY 11717
Phone: 631-389-1560
ljoseph@parkell.com

Contact Person: La-Shaunda Joseph – Compliance and Regulatory Manager
Date of Summary Preparation: January 19, 2022

2. Type of Submission: Traditional 510(k)

3. **Device**

Device Proprietary Name:	Parkell Self-Adhesive Cement
Common or Usual Name:	Self-Adhesive Cement
Classification Name:	Dental Cement
Regulation Number:	21 CFR 872.3275
Product Code:	EMA
Device Classification	II

4. **Primary Predicate Device**

Self-adhesive Cement (K073173, Dentsply International) (now marketed by Dentsply under the trade name “SmartCem2”).

5. Device Description

Parkell Self-Adhesive Cement is a two-component, dual-cured, self-etching, self-adhesive resin cement. It is designed for luting of indirect restorations (inlays, onlays, crowns, bridges, and endodontic posts) made of metal alloys, composite resins, porcelain, lithium disilicate or zirconia. The material also exhibits high bond strength and is radiopaque to allow visibility of excess in sub-gingival areas.

Parkell Self-Adhesive Cement will cure in 10 seconds with a dental curing light emitting blue light at 430 - 480 nm and a minimum intensity of 600 mW/cm^2. The product will self-cure in 3-4 minutes at mouth temperature.

Parkell Self-Adhesive Cement will be provided in 5 mL auto-mix syringes. The device comprises catalyst and base components, which are combined just prior to use via a static (1:1) mixing tip which is affixed to the dual chamber syringe.

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6. Indications for Use

Parkell Self-Adhesive Cement is intended for the cementation of indirect restoratives including ceramic, zirconia, composite, and metal-based inlays, onlays, crowns, bridges, and posts.

7. Comparison of Technological Characteristics

The standards applicable to the subject device and to the comparison of technological characteristics referenced within the submission, include ISO 4049:2019 Dentistry - *Polymer-based restorative materials*, ISO 11405:2015 Dentistry - *Testing of adhesion to tooth structure*, ISO 16506:2017 *Dentistry. Polymer-based luting materials containing adhesive components,* ISO 13116:2014 Dentistry — *Test method for determining radio-opacity of materials* and ISO 23317:2014 *Implants for surgery - In vitro evaluation for apatite-forming ability of implant materials*.

Information provided in these 510(k) submissions demonstrates that Parkell Self-Adhesive Cement is substantially equivalent to the Predicate *Self-adhesive Cement* (K073173) (now marketed by Dentsply under trade name, SmartCem2), in terms of similar intended use and technological characteristics (e.g. Compressive Strength, Depth of Cure, film thickness, flexural strength, Bond Strength, radiopacity, water sorption and solubility), wherein Parkell Self-Adhesive Cement differs from the Predicate Device in the minor ways detailed in this Submission.

Parkell's Self-Adhesive Cement has expanded its intended use beyond the predicate device to include zirconia. Parkell has conducted the necessary tests to illustrate the efficacy of the Bonding Substrates to Zirconia.

Any differences between the Device and the Predicate Device, for purposes of this 510(k) submission, do not raise new questions of efficacy or safety. Thus, this submission demonstrates the substantial equivalence between Parkell Self-Adhesive Cement to the Predicate device. A brief comparison of Parkell Self-Adhesive Cement to the Primary Predicate is provided in Table 5-A below.

Table 5-A: Comparison of Subject and Predicate Devices

Property	**Parkell Device** *Self-Adhesive Cement (Parkell, Inc.)*	**Primary Predicate Device** *510(k) no. K073173, SmartCem2, filed as "Self-adhesive Cement"*
Intended uses	Parkell Self-Adhesive Cement is intended for the cementation of indirect restorations including Ceramic, Zirconia, Composite and Metal-based inlays, onlays, Crowns, Bridges, and posts.	Self-adhesive Resin Cement is intended for the cementation of indirect restorations including Ceramic, Composite and Metal-based inlays, onlays, Crowns, Bridges and posts.
Classification Product Code	EMA	EMA
Regulation Number	872.3275	827.3275
Principle of operation	Self-adhesive cementation of indirect dental restorations	Self-adhesive cementation of indirect dental restorations
Material form	Paste	Paste

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Base/Catalyst Ratio	1:1	1:1
Polymerization Method	Dual-Cure	Dual-Cure
Ions released	Fluoride Calcium Phosphate	Fluoride
Radiographic Appearance	Radiopaque	Radiopaque
Delivery System	Auto-mix syringe	Auto-mix syringe
Film Thickness (Microns) Pass/Fail Criteria: ≤ 50 microns	≤ 50 microns	≤ 50 microns
Working time (seconds) @ 35 C Pass/Fail Criteria: ≤ 60 seconds	≤ 60 seconds	≤ 60 seconds
Setting time (minutes) @ 35 C Pass/Fail Criteria: ≤ 10 minutes	≤ 10 minutes	≤ 10 minutes
Flexural strength LC (MPa) Pass/Fail Criteria: ≥ 50 MPa	≥ 50 MPa	≥ 50 MPa
Flexural Strength SC (MPa) Pass/Fail Criteria: ≥ 50 MPa	≥ 50 MPa	≥ 50 MPa
Compressive Strength LC Pass/Fail Criteria: ≥ 200 MPa	≥ 200 MPa	≥ 200 MPa
Water Sorption (ug/mm^3) Pass/Fail Criteria: ≤ 40 ug/mm^3	≤ 40 ug/mm^3	≤ 40 ug/mm^3
Water Solubility (ug/mm^3) Pass/Fail Criteria: ≤ 7.5 u/mm^3	≤ 7.5 u/mm^3	≤ 7.5 u/mm^3
Radiopacity (% Al) Pass/Fail Criteria: ≥ 100 %Al	≥ 100 %Al	≥ 100 %Al
Depth of Cure (mm) Pass/Fail Criteria: ≥ 1mm	≥ 1mm	≥ 1mm
Diametral Tensile Strength (MPa) Pass/Fail Criteria: ≥ 30 MPa	≥ 30 MPa	≥ 30 MP
Barcol Hardness after 20 minutes @35c (MPa) Pass/Fail Criteria: > 50 MPa	> 50 MPa	> 50 MPa
Barcol Hardness after 20 secs Light Cure each surface (MPa) Pass/Fail Criteria: > 60 MPa	> 60 MPa	> 60 MPa
Film Thickness (Microns) Pass/Fail Criteria: ≤ 50 microns	≤ 50 microns	≤ 50 microns

Table 5-B: Comparison of Subject and Predicate Devices: Bond Strength to different Substrate

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Substrate Pass/Fail Requirements		**Parkell Device** *Self-Adhesive Cement (Parkell, Inc.)*	**Predicate Device** *510(k) no. K073173, SmartCem2, filed as "Self-Adhesive Cement"*
Bonding Substrates to Composite Stumps	**Treatment**	**Bond Strength (MPa)**	**Bond Strength (MPa)**
Dentin LC (Pass/Fail Criteria: ≥ 6 MPa)	None	≥ 6 MPa	≥ 6 MPa
Dentin LC (Pass/Fail Criteria: ≥ 10 MPa)	PBA	≥ 10 MPa	≥ 10 MPa
Dentin SC (Pass/Fail Criteria: ≥ 3 MPa)	None	≥ 3 MPa	≥ 3 MPa
Enamel LC (Pass/Fail Criteria: ≥ 10 MPa)	None	≥ 10 MPa	≥ 10 MPa
Enamel LC (Pass/Fail Criteria: ≥ 10 MPa)	H3PO4	≥ 10 MPa	≥ 10 MPa
Enamel SC (Pass/Fail Criteria: ≥ 3 MPa)	None	≥ 3 MPa	≥ 3 MPa
Lithium Disilicate LC (Pass/Fail Criteria: ≥ 5 MPa)	Silane	≥ 5 MPa	≥ 5 MPa
Lithium Disilicate LC (Pass/Fail Criteria: ≥ 10 MPa)	HF	≥ 10 MPa	N/A
Zirconia LC (Pass/Fail Criteria: ≥ 10MPa)	SB	≥ 10 MPa	≥ 10 MPa
Zirconia LC (Pass/Fail Criteria: ≥ 10 MPa)	PBA	≥ 10 MPa	N/A
Zirconia LC (Pass/Fail Criteria: ≥ 10MPa)	HF	≥ 10 MPa	N/A
Zirconia SC (Pass/Fail Criteria: ≥ 5 MPa)	SB	≥ 5MPa	≥ 5MPa
Porcelain LC (Pass/Fail Criteria: ≥ 10MPa)	SB	≥ 10 MPa	≥ 10 MPa
Porcelain LC (Pass/Fail Criteria: ≥ 10 MPa)	Silane	≥ 10 MPa	N/A
Porcelain LC (Pass/Fail Criteria: ≥ 10 MPa)	HF	≥ 10 MPa	N/A
Porcelain SC (Pass/Fail Criteria: ≥ 5 MPa)	HF	≥ 5 MPa	N/A
Palladium LC (Pass/Fail Criteria: ≥ 10 MPa)	SB	≥10 MPa	≥10 MPa
Titanium LC (Pass/Fail Criteria: ≥ 10 MPa)	SB	≥10 MPa	≥10 MPa
Titanium SC (Pass/Fail Criteria: ≥ 5 MPa)	SB	≥ 5 MPa	≥ 5 MPa
Cobalt LC (Pass/Fail Criteria: ≥ 10 MPa)	SB	≥ 10MPa	≥ 10MPa
Cobalt SC (Pass/Fail Criteria: ≥ 5 MPa)	SB	≥ 5 MPa	≥ 5 MPa

As seen above, the differences between the subject and primary predicate devices are limited to minor differences materials of construction and material form. These technological differences do not raise issues with respect to substantial equivalence and are addressed by comparative performance data provided within this submission.

8. Reference Devices

A table of the References devices used in this submission is shown below:

Table 5-C: FDA-cleared Reference Devices

Reference Device/Source	**FDA 510(k) number**
HelioSeal F (Ivoclar)	K190339
Activa Pit and Fissure Sealant (Pulpdent)	K172169
Clearfield Universal Bond Quick (Kuraray Dental Inc.)	K161042
Brush&Bond 4-Meta Bonding System (Parkell Inc.)	K151518

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Smartemp X1(Parkell Inc.)	K190930
HyperFil-LV (Parkell Inc.)	K182296
ESPE's Adper Easy Bond L-Pop dental adhesive (3M)	K020946
ESPE's Filtek Bulk Fill Posterior (3M)	K141081
RelyX luting plus automix (3M)	K111185
Aura (SDI)	K102984
Sonicfill 2 (Kerr)	K143209

9. Performance Testing

The following non-clinical studies were performed:

- Performance and Physical Properties
    - Bond strength using different substrates.
    - Compressive strength
    - Water sorption and solubility
    - Depth of Cure
    - Barcol Hardness
    - Flexural strength
    - Radiopacity
    - Working Time/Setting Time at Room Temperature and oral temperature
    - Calcium release
    - Fluoride release
    - Phosphate release
    - Film Thickness
    - Viscosity
    - Shelf Life
    - Bioactivity
    - Microleakage
    - Ions Release and Recharge
    - Gap Closure

10. **Biocompatibility and Bench Data**

An evaluation of biocompatibility was addressed for the safety of Parkell Self-Adhesive Cement in accordance with ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-5: 2009, ISO 10933-6:2016, ISO 10993-10: 2010, ISO 10993-11:2017, ISO 10993-12: 2012, ISO 10993-33:2015 and the FDA's Guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 4, 2020). The following table shows the tests that were conducted on the subject device.

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Cytotoxicity	*ISO 10993-5*
Acute Systemic Toxicity Test	*ISO 10993-11*
Primary oral (Buccal) irritation test	*ISO 10993-10*
Genotoxicity Test	*ISO 10993-3*
Sensitization Test	*ISO 10993-10*
Implantation Test	*ISO 10993-6*

The conclusion of the evaluation is that Parkell Self-Adhesive Cement is substantially equivalent to the predicate device in terms of biocompatibility.

11. Clinical Performance Data

There was no clinical testing required to support the Device as the intended uses are equivalent to the Predicate Device. These types of devices 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:

The information provided above supports that Parkell Self-Adhesive Cement is substantially equivalent to the Primary Predicate. Although minor differences in design and technology exist between the subject and primary predicate devices, the testing supports that these differences do not raise questions as to the substantial equivalence between the devices. Therefore, it is concluded that Parkell Self-Adhesive Cement is substantially equivalent to the Primary Predicate.