August 8, 2025

Parkell, Inc.
% Keith Barritt
Attorney
Fish & Richardson P.C.
1000 Maine Avenue, S.W.
Suite 1000
Washington, District of Columbia 20024

Re: K243254
Trade/Device Name: Parkell Pit and Fissure Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit And Fissure Sealant And Conditioner
Regulatory Class: Class II
Product Code: EBC
Dated: July 8, 2025
Received: July 8, 2025

Dear Keith Barritt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

k243254

Device Name

Parkell Pit and Fissure Sealant

Indications for Use *(Describe)*

The Parkell Pit and Fissure Sealant is indicated for prophylactic sealing of pits and fissures as well as for micro-restorative procedures for composite restorations.

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.

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

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510(k) Summary -K243254

Parkell, Inc.
Parkell Pit and Fissure Sealant

Submitter

(i) 510(k) Submitter

Parkell, Inc.
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Edgewood, NJ 11717
FDA Registration No. 2411797

(ii) 510(k) Submitter Contact

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(iii) Preparation Date

August 8, 2025

Device

Trade or Proprietary Name:	Parkell Pit and Fissure Sealant
Common Name:	pit and fissure sealant and conditioner
Classification Name:	sealant, pit and fissure, and conditioner
Product Code:	EBC, 21 CFR 872.3765
Class:	2

Predicate Device

The Parkell Pit and Fissure Sealant device (the "Device") is substantially equivalent to Premier Dental Company Products' "Premier Sealant" (K#161580, the "Predicate Device").

The Device is indicated for "prophylactic sealing of pits and fissures as well as for micro-restorative procedures." The Indications for Use statement for the Predicate Device is nearly identical, namely "prophylactic sealing of pits and fissures. It may also be used for micro-restorative or initial layer of composite restorations." The minor difference in wording is irrelevant and at most is narrowing, as the Indications for Use for the Device does not refer to "or initial layer" as does the Indications for Use for the Predicate Device.

Device Description

The Device is a light-cured, flowable, resin-based sealant for prophylactic sealing of pits and fissures as well as for micro-restorative procedures. The Device is light-curable under standard power (600 mW/cm^2) and contains filling agents which cause the Device to release and recharge beneficial ions (fluoride and calcium).

The device is intended for use by licensed healthcare professionals only. The device does not come sterilized and is not intended to be sterilized prior to use.

Indications for Use

The Device is indicated for prophylactic sealing of pits and fissures as well as for micro-restorative procedures for composite restorations.

Comparison of Technological Characteristics

The Device has the same basic technological characteristics in terms of design, material, and chemical composition as the Predicate Device and is substantially equivalent thereto as shown below:

Property	**Parkell Device** *Pit and Fissure Sealant (Parkell, Inc.) K243254*	**Predicate Device** *510(k) no. K161580, BioCoat, filed as "Premier Sealant" (Premier Dental Company)*
Intended uses	Parkell Pit and Fissure Sealant is indicated for prophylactic sealing of pits and fissures as well as for micro-restorative procedures for composite restorations.	Premier Sealant, a prescription only medical device used for prophylactic sealing of pits and fissures. It may also be used for micro-restorative or "initial layer" of composite restorations
Classification Product Code	EBC	EBC
Regulation Number	872.3765	872.3765
Principle of operation	Prophylactic sealing of pits and fissures	Prophylactic sealing of pits and fissures
Material form	Low viscosity paste	Low viscosity paste
Polymerization Method	Light-Cure	Light-Cure
Curing Time	20 sec	20 sec
Delivery System	1.2 mL syringe	1.2 mL syringe
Bond Strength to Dry Enamel (MPa) Pass/Fail Criteria: ≥10 MPa	≥10 MPa	≥10 MPa
Compressive Strength (MPa) Pass/Fail Criteria: ≥200MPa	≥200MPa	≥200MPa
Flexural Strength (MPa) Pass/Fail Criteria: ≥90MPa	≥90MPa	≥90MPa
Depth of cure (mm) Pass/Fail Criteria: 1.5-2.5mm	1.5-2.5mm	1.5-2.5mm
Shrinkage (%) Pass/Fail Criteria: ≤8%	≤8%	≤8%
Viscosity (initial) (Pa.S) Pass/Fail Criteria: 1-5Pa.s.	1-5Pa.s	1-5Pa.s
Beneficial Ion Release and Recharge	Fluoride Calcium	Fluoride Calcium Phosphate
Accessories	Applicator tip	Applicator tip

Shelf Life Testing

The Device has been tested to establish a shelf life of two years.

Material And Chemical Composition

The Device does come into direct contact with the patient. Though the precise composition is confidential, the Device contains monomers, fillers, photoinitiator/coactivators, a calcium donor, inhibitor, fluorescence agent, and colorant, and is substantially equivalent to the Predicate Device in terms of ingredients and biocompatibility.

Performance Data Summary

Non-clinical testing of the physical properties of the Device was conducted. There were no clinical tests performed for the Device.

A comparison of the Device with the Predicate Device is shown in the table below:

Property	**Parkell Device** *Pit and Fissure Sealant (Parkell, Inc.) K243254*	**Predicate Device** *510(k) no. K161580, BioCoat, filed as "Premier Sealant" (Premier Dental Company)*
Intended uses	Parkell Pit and Fissure Sealant is indicated for prophylactic sealing of pits and fissures as well as for micro-restorative procedures for composite restorations.	Premier Sealant, a prescription only medical device used for prophylactic sealing of pits and fissures. It may also be used for micro-restorative or "initial layer" of composite restorations
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Flexural Strength (MPa) Pass/Fail Criteria: ≥90MPa	≥90MPa	≥90MPa
Depth of cure (mm) Pass/Fail Criteria: 1.5-2.5mm	1.5-2.5mm	1.5-2.5mm
Shrinkage (%) Pass/Fail Criteria: ≤8%	≤8%	≤8%
Viscosity (initial) (Pa.S) Pass/Fail Criteria 1-5Pa.s.	1-5Pa.s	1-5Pa.s
Beneficial Ion Release and Recharge	Fluoride Calcium	Fluoride Calcium Phosphate
Accessories	Applicator tip	Applicator tip

Conclusion

Based on the non-clinical testing conducted of the physical properties of the Device in comparison to the Predicate Device identified above, and based on the biocompatibility of ingredients for the Device, Parkell concludes that the Device is substantially equivalent to the Predicate Device.