November 22, 2019

Parkell, Inc.
David Mott
Vice President - Legal, R&D, and Regulatory
300 Executive Drive
Edgewood, New York 11717

Re: K191103

Trade/Device Name: Parkell Desensitizer Gel
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: Class II
Product Code: EJK, LBH
Dated: October 24, 2019
Received: October 25, 2019

Dear 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. 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.


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,

Michael E. Adjodha -S

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K191103

Device Name
Parkell® Desensitizer Gel

Indications for Use (Describe)
Parkell® Desensitizer Gel is indicated for reduction of tooth hypersensitivity by the following treatments:
• treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease, and/or acid erosion;
• treatment of dentin after mechanical tooth cleaning, scaling, and/or root planning;
• treatment of tooth hypersensitivity associated with bleaching; and
• treatment of prepared dentin for fillings and/or prosthetic 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.

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1. **Submitter**

Parkell, Inc.
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Phone: 631-389-1545
Fax: 631-389-1546
dmott@parkell.com

Contact Person: David Mott, Vice President – Legal & Regulatory
Date of Initial Submission: April 24, 2019
Date of Submission of Final Revision: October 24, 2019

2. **Device**

Device Proprietary Name: Parkell® desensitizer
Common or Usual Name: Tooth desensitizer
Classification Name: Calcium hydroxide cavity liner
Regulation Number: 21 CFR 872.3250
Product Code: EJK
Device Classification II

3. **Primary Predicate**

Teethmate Desensitizer, K131068, Kuraray Noritake Dental Inc.

4. **Device Description**

Parkell® Desensitizer Gel alleviates dental hypersensitivity at treatment sites. It is a gel which requires no mixing prior to use and which is applied to treatment sites using a standard applicator brush. Parkell® Desensitizer releases calcium and phosphate ions at the treatment site and stimulates hydroxyapatite formation on the surface of treated dentin and in dentinal tubules. In this manner, the Device hardens following application and forms a layer of mineral hydroxyapatite as well as hydroxyapatite plugs which occlude dentinal tubules, which results in the treatment of dental hypersensitivity.

Parkell® Desensitizer Gel is packaged in any standard single-chamber syringe. The syringe is accompanied by standard snap-in tips and standard applicator brushes.
5. Indications for Use

Parkell® Desensitizer Gel is indicated for reduction of tooth hypersensitivity by the following treatments:

- treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease, and/or acid erosion;
- treatment of dentin after mechanical tooth cleaning, scaling, and/or root planning;
- treatment of tooth hypersensitivity associated with bleaching; and
- treatment of prepared dentin for fillings and/or prosthetic restorations.

6. Comparison of Technological Characteristics

Information provided in this 510(k) submission demonstrates that Parkell® Desensitizer Gel is substantially equivalent to the Primary Predicate (Teethmate Desensitizer, K131068), in terms of the intended use and technological characteristics.

Any differences between the Device and the Primary Predicate, for purposes of this 510(k) submission, are of a minor nature as is demonstrated in Table 5-A and throughout this submission. Thus, this submission demonstrates the substantial equivalence between Parkell® desensitizer and the Primary Predicate. A brief comparison of Parkell® Desensitizer Gel to the Primary Predicate is provided below:

Table 5-A:

<table>
<thead>
<tr>
<th>Property</th>
<th>Parkell® Desensitizer Gel (Parkell, Inc.)</th>
<th>Primary Predicate Teethmate Desensitizer (K131068, Kuraray Noritake Dental Inc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended uses</td>
<td>Parkell® Desensitizer Gel is indicated for reduction of tooth hypersensitivity by the following treatments:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease, and/or acid erosion;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• treatment of dentin after mechanical tooth cleaning, scaling, and/or root planning;</td>
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<td></td>
<td>• treatment of tooth hypersensitivity associated with bleaching; and</td>
<td></td>
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<td></td>
<td>• treatment of prepared dentin for fillings and/or prosthetic restorations.</td>
<td></td>
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<tr>
<td>Classification</td>
<td>EJK</td>
<td>EJK</td>
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<tr>
<td>Product Code</td>
<td></td>
<td></td>
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<tr>
<td>Regulation Number</td>
<td>21 CFR 872.3250</td>
<td>21 CFR 872.3250</td>
</tr>
<tr>
<td>Principle of</td>
<td>tooth desensitizer</td>
<td>tooth desensitizer</td>
</tr>
<tr>
<td>operation</td>
<td></td>
<td></td>
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<tr>
<td>Material form</td>
<td>gel</td>
<td>powder/liquid</td>
</tr>
</tbody>
</table>
As seen above, the differences between the subject and primary predicate devices are limited to 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.

7. Biocompatibility and Bench Data


8. 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.

9. Statement of Substantial Equivalence:

The information provided above supports that Parkell® Desensitizer Gel 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® Desensitizer Gel is substantially equivalent to the Primary Predicate.