September 5, 2019

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

Re: K190930
Trade/Device Name: SmarTemp X1
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, POW
Dated: June 5, 2019
Received: June 7, 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.

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,

Michael Adjodha
Acting Assistant 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

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)*
K190930

Device Name
SmarTemp® X1

Indications for Use *(Describe)*
SmarTemp® X1 is a self-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers. SmarTemp® X1 is intended for the fabrication of: temporary crowns, bridges, inlays, onlays, long-term temporaries, and temporary veneers.

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

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Phone: 631-389-1545
dmott@parkell.com

Contact Person: David Mott, Vice President – Legal, R&D, and Regulatory
Date of Original Submission: April 9, 2019
Date of Latest Revision: September 5, 2019

2. Device

Device Proprietary Name:	SmarTemp® X1
Common or Usual Name:	Temporary crown and bridge resin
Classification Name:	Temporary crown and bridge resin
Regulation Number:	21 CFR 872.3770
Product Code:	EBG
Device Classification	II

3. Predicate Device

Luxatemp® Ultra/Star, K101710, DMG USA, Inc.

4. Device Description

SmarTemp® X1 is a self-curing, resin-based composite, suitable for the fabrication of temporary crowns, bridges, inlays, onlays, and veneers. It is a bis-acryl resin-based material comprising a 10:1 ratio of base to catalyst components, which when expressed by the user from dual-chamber syringes or cartridges mix through standard snap-in accessory mixing tips. SmarTemp® X1 self-cures in approximately 6 minutes at mouth temperature.

SmarTemp® X1 is packaged in any standard, opaque, dual-chamber syringe or cartridge suitable for containing a 10:1 ratio of base and catalyst components, respectively. The syringe or cartridge is accompanied by standard snap-in automix tips.

5. Indications for Use

SmarTemp® X1 is a self-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers. SmarTemp® X1 is intended for the fabrication of: temporary crowns, bridges, inlays, onlays, long-term temporaries, and temporary veneers.

6. Comparison of Technological Characteristics

Information provided in this 510(k) submission demonstrates that SmarTemp® X1 is substantially

equivalent to the Predicate Device (Luxatemp® Ultra/Star, K101710) in terms of critical properties for provisional materials, such as, for example, compressive strength, flexural strength, volumetric shrinkage, water sorption, and water solubility.

As is demonstrated throughout this submission and below in Table 5-A, any differences between the Device and the Predicate Device in the chemical make-up and/or physical properties, do not raise questions of substantial equivalence. Thus, this submission demonstrates the substantial equivalence between SmarTemp® X1 and the Predicate Device. A brief comparison of SmarTemp® X1 to the Predicate Device is provided below:

Table 5-A:

Property	**SmarTemp® X1** (Parkell, Inc.)	**Predicate Device** Luxatemp® Ultra/Star (K101710, DMG USA, Inc.)
Intended uses	SmarTemp® X1 is a self-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers. SmarTemp® X1 is intended for the fabrication of: • temporary crowns • bridges • inlays • onlays • long-term temporaries • temporary veneers.	Luxatemp® Ultra/Star is a self-curing or dual-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers. Luxatemp® Ultra/Star is intended for the fabrication of: • temporary crowns • bridges • inlays • onlays • long-term temporaries • temporary veneers. Luxatemp® Ultra/Star is also intended for incorporation of most mechanically anchored attachment components into the acrylic base of a denture, an overdenture, or partial denture.
Classification Product Code	EBG	EBG
Regulation Number	21 CFR 872.3770	21 CFR 872.3770
Principle of operation	Temporary crown and bridge resin	Temporary crown and bridge resin
Base/Catalyst Ratio	10:1	10:1
Self-curing	Yes	Yes
Radiopaque	Yes	Yes
Exhibits fluorescence	Yes	Yes
Compressive Strength (>300 MPa)	>300 MPa	>300 MPa
Flexural Strength (>100 MPa)	>100 MPa	>100 MPa

Table 5-A (continued):

Property	SmarTemp® X1 (Parkell, Inc.)	Predicate Device Luxatemp® Ultra/Star (K101710, DMG USA, Inc.)
Shrinkage (< 3%)	< 3%	< 3%
Water Sorption (≤ 40 μg/mm^3)	≤ 40 μg/mm^3	≤ 40 μg/mm^3
Water Solubility (≤ 7.5 μg/mm^3)	≤ 7.5 μg/mm^3	≤ 7.5 μg/mm^3
Chemical composition	dimethacrylate based composite resin, comprising filler component(s)	dimethacrylate based composite resin, comprising filler component(s)

7. Non-clinical Performance Testing

a. Biocompatibility

An evaluation of biocompatibility was conducted for SmarTemp® X1 in accordance with ISO 10993-1: 2009, ISO 10993-3: 2014, ISO 10993-5: 2009, ISO 10993-10: 2010, ISO 10993-11:2017, ISO 10993-12: 2012, ISO 10993-33: 2015, BS ISO 23317:2014, ISO/IEC 17025:2017, OECD 471, 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" (June 16, 2016).

b. Shelf life

Testing was conducted to evaluate the shelf life of SmarTemp® X1.

c. Bench Performance

Testing was conducted on both SmarTemp® X1 and the predicate device (Luxatemp® Ultra/Star, K101710) to evaluate critical properties including compressive strength, flexural strength, volumetric shrinkage, water sorption, and water solubility.

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 SmarTemp® X1 is substantially equivalent to the Predicate Device. Although minor differences in design and technology may exist between the subject and predicate devices, the testing supports that these differences do not raise any questions with respect to substantial equivalence. Therefore, it is concluded that SmarTemp® X1 is substantially equivalent to the Predicate Device.