July 31, 2020

DeltaMed GmbH
% Gary Chuven
Director of Regulatory Affairs
Cosmedent, Inc
401 N Michigan Ave, Suite 2500
Chicago, Illinois 60611

Re: K200039
Trade/Device Name: P pro Crown & Bridge
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: June 22, 2020
Received: July 6, 2020

Dear Gary Chuven:

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 Srinivas "Nandu" Nandkumar, Ph.D.
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)*
K200039

Device Name
P pro Crown & Bridge

Indications for Use *(Describe)*
Additive production of temporary anterior and posterior restorations, e.g.
- Single tooth crowns.
- Bridges (max. six units, max. two consecutive pontics).
- Veneers, Inlays, Onlays.

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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Section 5:
510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c)

510(k) No.: K200039

Date Prepared: 2020-07-29

501(k) Submitter:
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Trade Names: P pro Crown & Bridge

Common Name: Crown and bridge, temporary, resin

Regulatory Class: Class II

Device Panel: Dental Panel

Regulation Number: 21 CFR 872.3770

Classification Name: Temporary crown and bridge resin

Product Code: EBG

Predicate Devices:

(1) Primary Predicate	e-Dent Temporary; DeltaMed GmbH, Friedberg, DE
(2) Predicate Device	Vita CAD-Temp for in Lab; VITA Zahnfabrik GmbH & Co KG, Säckingen, GE
(3) Predicate Device	Luxatemp Ultra/Luxatemp Star; DMG Inc., Ayer Ma, USA

Description of Device:

P pro Crown & Bridge is a flowable, light-curing, acrylate-based composite material for the additive production of temporary anterior and posterior restorations.

It consists of multifunctional acrylic resins and fillers made of inorganic fillers ranging in size from 0.04 – 0.2 µm. The raw materials used in the preparation have been used for many years in dental products.
Exposition: The temporary crown and bridge resin has an intended gingival, enamel/dentine contact for more than 30 days.

Intended Use:

P pro Crown & Bridge is a flowable, light-curing, acrylate-based composite material for the additive production of temporary anterior and posterior restorations.

Indications for Use:

Additive production of temporary anterior and posterior restorations, e.g.
- Single-tooth crowns.
- Bridges (max. six units, max. two consecutive pontics).
- Veneers, inlays, onlays.

Biocompatibility testing

The biocompatibility evaluation for P pro Crown & Bridge was conducted in accordance with the Guidance Document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and the International Standard ISO 10993-1:2018(R) 2019 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)

According to ISO 10993-2 "Biological evaluation of medical devices —Animal welfare requirements" no additional animal testing were necessary to ensure human safety. For the evaluation of the biological risk of endpoints: systemic- and CMR toxicity, sufficient literature data were available.

Substantial Equivalence Discussion:

Subject Device **:** P pro Crown & Bridge

(1) Primary Predicate Device **:** e-Dent Temporary
(2) Predicate Device **:** Vita CAD-Temp, for in Lab
(3) Predicate Device **:** Luxatemp Ultra / Luxatemp Star

Submission:	Class. Name:	Product Code	Regulation No.
(1) K102776	Crown and Bridge, Temporary, Resin	EBG	872.3770
(2) K070991	Crown and Bridge, Temporary, Resin	EBG	872.3770
(3) K101710	Crown and Bridge, Temporary, Resin	EBG	872.3770

The table on the following page compares the subject device with its predicates:

Table 5.2 Analysis of substantial equivalence

Property	Subject Device	(1) Primary Predicate	(2) Predicate Device	(3) Predicate Device
	P pro Crown & Bridge	**e-Dent Temporary (K102776)**	**Vita CAD-Temp for inLab (K070991)**	**Luxatemp Ultra / Star (K101710)**
Intended use, Indications	Additive production of temporary anterior and posterior restorations, e.g. Single-tooth crowns. Bridges (max. six units, max. two consecutive pontics). Veneers, inlays, onlays.	e-dent Temp is used for the fabrication of multi-unit, fully or partially anatomical long-term temporary crown and bridge restorations, anterior crowns, posterior crowns, anterior/posterior bridges 3 or 4 units, 1 pontic	CAD-Temp is used for the fabrication of multi-unit, full or partial anatomical long term temporary bridge restorations with up to 2 pontics using the inLab or CEREC systems of Sirona. The bridge block can also be used for temporary crowns.	Self-curing composite for the fabrication of temporary crowns and bridges, inlays, onlays and veneers.
Processing	Additive manufacturing, using printers with 385 nm wavelength	Additive manufacturing using Perfactory DDP, 350-420nm; (Dental Digital Printer), Envisiontec GmbH, Germany	Substractive (mechanical) processing	Self-curing composite
Requirements **1. ISO 4049** **2. ISO 10477**	**Mechanical Properties according to ISO 4049 and ISO 10477**			
Flexural strength	146 MPa	123 MPa	> 80 MPa	125 MPa
1. ≥ 100 MPa	pass	pass	./.	pass
2. ≥ 50 MPa	pass	pass	pass	pass
Solubility	0.5 µg/mm3	0 µg/mm3	No data	No data
1. & 2. **≤ 7,5 µg/mm3**	pass	paas	Complies with ISO 10477	---
Water absorption	16 µg/mm3	18 µg/mm3	No data	10 µg/mm3
1. & 2. **≤ 40 µg/mm3**	pass	pass	Complies with ISO 10477	pass
Color stability **1. & 2.**	pass	pass	Complies	No data
Requirements	**Mechanical Properties according to DeltaMed internal standard**			
Compressive Strength (MPa)	358 MPa	354 MPa	n.e.	376 MPa
> 300 MPa	pass	pass	---	pass

Property	Subject Device	(1) Primary Predicate	(2) Predicate Device	(3) Predicate Device
	P pro Crown & Bridge	**e-Dent Temporary (K102776)**	**Vita CAD-Temp for inLab (K070991)**	**Luxatemp Ultra / Star (K101710)**
Modulus of elasticity	5988 MPa	5300 MPa	>2800 MPa	No data
> 5000 MPa	pass	pass	./.	---
Composition/Chemical properties				
	Acrylate monomers with initiators, stabilizers and pigments, approx. 50% inorganic fillers		Modified polymethacrylates with 14% inorganic filler	Matrix of multi-functional methacrylates; catalysts, stabilizers and additives

Discussion:

Primary Predicate Device: All four products have substantially the same intended use as temporary esthetic (dental) restorative materials but differ in the indication for use. The predicate device (1) as the primary predicate device is used to demonstrate substantially equivalence in manufacturing method, indication (fully or partially anatomical long-term temporary crown and bridge -but limited by 4 units and 1 ponic), chemical- and biological properties.

(2) Reference Device: Is referenced based on its physical properties to demonstrate equivalence of the expanded indication of 2 pontics.

(3) Predicate Device: Concerning the additional claims (indications) “veneers, inlays, onlays”, was selected to show the equivalence with the subject device.

The physical, mechanical and chemical properties of the subject device, the primary predicate device (K102776) and the two predicate devices (K070991 and K101710) are very similar.
Although the indication refers to temporary restoration, the subject device complies with the standards ISO 4049 (Polymer-based restorative materials) and ISO 10477 (Polymer-based crown and veneering materials) in terms of flexural strength, water sorption, solubility and color stability.

Biocompatibility studies were performed on the subjected device. The data were analyzed and the results of the biocompatibility test (10993-xx) substantiate that P pro Crown & Bridge with its modification in composition is as safe (biocompatible) as the primary predicate.

Results/summary of the Substantial Equivalence

The subject device P pro Crown & Bridge has been compared with its primary predicate device e-Dent Temporary (K102776) and the two predicate devices- Vita CAD-Temp for inLab (K070991) and Luxatemp Ultra / Star (K101710), with regard to indication (intended use), performance data, chemical composition and biocompatibility.
It can be concluded, that the subject device P pro Crown & Bridge is substantially equivalent to the predicates.