January 21, 2022

Saremco Dental AG
% Nevine Erian
Principal Regulatory Consultant
BQC Consulting, LLC
24341 Barbados Dr.
Dana Point, California 92629

Re: K213343
Trade/Device Name: Saremco Print CROWNTEC
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBF, EBG, PZY
Dated: January 5, 2022
Received: January 5, 2022

Dear Nevine Erian:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

k213343

Device Name

saremco print Crowntec

Indications for Use *(Describe)*

saremco print CROWNTEC is a light-curing 3D-printed material intended as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The saremco print CROWNTEC material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations. saremco print CROWNTEC can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

Type of Use *(Select one or both, as applicable)*

X 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 - K213343

Submitter	**Saremco Dental AG** Gewerbestrasse 4 CH-9445 Rebstein, Switzerland Establishment Reg. No. N/A
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Official Correspondent	Nevine Erian Regulatory Consultant **BQC Consulting, LLC** 24341 Barbados Dr. Dana Point, CA 92629 **Phone** (949) 370-7155 **Fax** (949) 240-8829 **E-mail** nevine@bqcconsulting.com

Date Prepared	October 4, 2021

Trade/Device Name	saremco print CROWNTEC
Common Name	Crown, Bridge and Denture Teeth Material
Classification Names & Regulation Numbers	Tooth Shade Resin Material – 21 CFR 872.3690 Temporary Crown and Bridge Resin – 21 CFR 872.3770 Preformed Plastic Denture Tooth – 21 CFR 872.3590
Product Codes	EBF & EBG
Subsequent Product Code	PZY

Predicate Devices

TERA HARZ (Graphy Inc.) – K202846 – ***Primary Predicate***

VarseoSmile Crown^{plus} (BEGO Bremer Goldschlägerei) – K201668 – ***Reference Predicate***

Dentca Denture Teeth (Dentca, Inc.) K172398 – ***Secondary Predicate***

Device Description

saremco print CROWNTEC is a resin-based material for the production of permanent and temporary restorations, veneers and artificial teeth on 3D printers. The material is an alternative to traditional heat-cured and auto polymerization resins. It requires a computer-aided and manufacturing (CAD/CAM) system including scanner, design software, additive printer and a post-curing unit.

Statement of Intended Use

saremco print CROWNTEC is a methacrylate-based material for 3D printing of dental restorations.

Statement of Indication for Use

saremco print CROWNTEC is a light-curing 3D-printed material intended as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The saremco print CROWNTEC material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations. saremco print CROWNTEC can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

Material Composition

saremco print CROWNTEC is composed of methacrylate-based resins, dental glass-filler, photo initiators and pigments.

Technological Characteristics

saremco print CROWNTEC is a light-curing resin for 3D printing.

Non-Clinical Performance Testing

saremco print CROWNTEC was tested and met the applicable requirements of the following ISO standard:

- ISO 4049:2019 – Dentistry – Polymer-based restorative materials
- ISO 10477:2020 – Dentistry – Polymer-based crown and veneering materials
- ISO 22112:2017 – Dentistry – Artificial teeth for dental prostheses

Bench test results allowed us to conclude that saremco print CROWNTEC meets its intended use.

Biocompatibility

saremco print CROWNTEC meets the biocompatibility requirements of the following standards:

- ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 7405:2018 Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Clinical Performance Data

The performance of methacrylate-based polymer resins in the clinical environment has been well established. No human clinical testing was performed to support the substantial equivalence of saremco print CROWNTEC.

Substantial Equivalence

The technical characteristics of saremco print CROWNTEC is substantially equivalent to the predicate devices.

Material

saremco print CROWNTEC is a resin-based material as the predicate devices.

Physical Properties

saremco print CROWNTEC has similar physical properties as the predicate devices.

Comparison of saremco print CROWNTEC to Predicate Devices

Attribute	saremco print CROWNTEC	TERA HARZ	VarseoSmile Crown^{plus}	DENTCA Denture Teeth
Indications				
Intended for both anterior and posterior restorations, including occlusal surfaces.	Yes	Yes	Yes	No
Used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	Yes	Yes	Yes	No
Used for the fabrication of artificial teeth	Yes	No	No	Yes
Used for the fabrication of temporary crowns & bridges.	Yes	Yes	No	No
Physical Properties				
Product State	Liquid	Liquid	Liquid	Liquid

Attribute	saremco print CROWNTEC	TERA HARZ	VarseoSmile Crown^{plus}	DENTCA Denture Teeth
Material Type	Methacrylate based resin	Methacrylate based resin	Methacrylate based resin	Methacrylate based resin
Material Color	Various Shades	Various Shades	Various Shades	Various Shades
Flexural Strength	Avg. ≥ 135 MPa	Avg. 148.73 MPa	≥ 116 MPa	> 50 MPa
Performance Testing	ISO 4049 ISO 10477 ISO 22112	ISO 4049 ISO 10477	ISO 4049 ISO 10477	ISO 22112
Material Attributes				
Chemical Characterization	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	Polyurethane Resin, Methacrylate, Dimethacrylate, Phosphine oxide, Butylated hydroxytoluene and Pigments	Methacrylate-based resins, dental glass-filler, photo initiators and pigments.	Methacrylate monomer, Propylidynetrimethyl trimethacrylate Urethane methacrylate, Initiators, pigments
Shelf Life	3 years	1 year	2 years	2 years
Storage Conditions	Do not expose to light	Do not expose to light	Do not expose to light	Do not expose to light
Storage Temperature	4-28°C (39-82°F)	15-25°C (60-77°F)	4-28°C (39-82°F)	15-25˚C (60-77˚F)

Attribute	saremco print CROWNTEC	TERA HARZ	VarseoSmile Crown^{plus}	DENTCA Denture Teeth
Technical Attributes				
Product Code(s)	EBF, EBG & PZY	EBF & EBG	EBF	PZY
Fabrication Method	Additive 3D printing	Additive 3D printing	Additive 3D printing	Additive 3D printing
UV Laser Wavelength	385 or 405 nm	385 or 405 nm	405 nm	385 nm
Layer Thickness when Printing	50 µm	50 or 100 µm	50 µm	50 or 100 µm
Polymerization Method	UV Curing Light	UV Curing Light	UV Curing Light	UV Curing Light
Sterile	No	No	No	No
Single Use	No	No	No	No
Rx or OTC	Rx	Rx	Rx	Rx

The differences in the physical properties and chemical compositions between saremco print CROWNTEC and the predicate devices do not impact safety and effectiveness, as the finished clinical product is a custom-fitted biocompatible restoration regardless of the material variation.

Conclusion

Information provided in this application demonstrates that saremco print CROWNTEC is substantially equivalent to the predicate devices. saremco print CROWNTEC shares the same indications for use, similar material composition, similar physical properties and technological characteristics as the predicate devices.