November 9, 2023

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K233596
Trade/Device Name: VarseoSmile TriniQ
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBG, PZY
Dated: November 8, 2023
Received: November 8, 2023

Dear Prithul Bom:

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 E. Adjodha -S

Michael E. Adjodha, MChE, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K233596

Device Name
VarseoSmile TriniQ

Indications for Use *(Describe)*

VarseoSmile TriniQ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile TriniQ material is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. VarseoSmile TriniQ can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

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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K233596

510(k) Summary
BEGO
VarseoSmile TriniQ
11/2/2023

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	VarseoSmile TriniQ
Regulation Name:	Material, Tooth Shade, Resin
Regulation Number:	21 CFR 872.3690
Device Class:	Class II
Product Code:	EBF
Secondary Product Code:	EBG, PZY
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device in this submission is substantially equivalent in indications, use and design principles to the following Predicate device.

510(k)	Predicate Device Name	Company Name
K213343	saremco print CROWNTEC	Saremco Dental AG

510(k)	Reference Device Name	Company Name
K201668	VarseoSmile Crown ^{Plus}	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG

INDICATIONS FOR USE

VarseoSmile TriniQ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile TriniQ material is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. VarseoSmile TriniQ can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

DEVICE DESCRIPTION

The Subject device is a light-cured methacrylate-based resin used in 3D printers to produce permanent or dental restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations including occlusal surfaces. The Subject device is used by a dentist or dental technician for the CAD/CAM manufacturing of temporary or permanent dental restorations.

Restorations fabricated using the Subject device are one-time use, prescription-only devices.

Commonly used dental CAD software is used by dental professionals to virtually design a fixed indirect restoration and generate an industry standard "STL" 3D dataset which reflects the intended shape and contour. The Subject resin is used within a validated manufacturing workflow to create the intended restoration. The Subject device is available in a variety of optional shades to reproduce the intended tooth shade of the restoration. Methacrylates are known materials, commonly used in the dental industry for fixed and removable prosthetic devices due to their physical-chemical, mechanical, and biocompatible properties.

The Subject device is intended to be sold by the bottle and used with compatible hardware in computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Predicate device with respect to Indications for Use and technological principles. The comparison tables below compare the Indications for Use and Technological Characteristics of the Subject, Predicate and Reference devices.

Indications For Use

Device	Indications for Use Statement
Subject Device VarseoSmile TriniQ BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG	*VarseoSmile TriniQ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile TriniQ material is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. VarseoSmile TriniQ can also be used for the fabrication of artificial teeth and temporary crowns & bridges.*
Predicate Device saremco print CROWNTEC (K213343) Saremco Dental AG	*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.*
Reference Device VarseoSmile Crown ^{Plus} (K201668) BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG	*VarseoSmile Crown ^{plus} is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile Crown ^{plus} material is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.*

The Subject and Predicate Indications for Use Statement (IFUS) are highly similar, differing only in the device name. The Reference device IFUS is similar in wording, with a similar usage of the material, but focusing only on permanent restorations. Slight differences in the wording of the device name within Indications for Use Statements does not change the intended use of the Subject and Predicate devices to fabricate temporary or permanent dental restorations.

Technological Characteristics

Parameter	Subject Device VarseoSmile TriniQ BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG	Predicate Device saremco print CROWNTEC (K213343) Saremco Dental AG	Reference Device VarseoSmile Crown Plus (K201668) BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG	Comparison with Predicate Device
Reason for Predicate/Reference	n/a	IFUS, Usage	Biocompatibility	***Same***
Product Code	EBF, EBG, PZY	EBF, EBG, PZY	EBF	***Same***
Regulation Number	872.3690	872.3690	872.3690	***Same***
Regulatory Class	Class II	Class II	Class II	***Same***
Intended Use	A methacrylate-based material for 3D printing (extra-oral light curing) of dental restorations.	saremco print CROWNTEC is a methacrylate-based material for 3D printing of dental restorations.	An indirect methacrylate-based restorative material used in conjunction with extra-oral light curing equipment for both anterior and posterior restorations, including occlusal surfaces. It is intended to be used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	***Highly Similar***
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	***Same***
Material Type	Methacrylate-based polymer resin	Methacrylate-based polymer resin	Methacrylate-based polymer resin	***Same***
Material Shades	Common VITA-shades	Common VITA-shades	Common VITA-shades	***Same***
Biocompatible	Yes	Yes	Yes	***Same***
OTC or Rx	Rx	Rx	Rx	***Same***
Sterile	Non-sterile	Non-sterile	Non-sterile	***Same***
Chemical Composition	Methacrylate-based resins, dental glass filler, photo initiators and pigments.	Methacrylate-based resins, dental glass filler, photo initiators and pigments.	Methacrylate-based resins, dental glass filler, photo initiators and pigments.	***Same***
Polymerization (Curing) Method	UV light, 385 or 405 nm w/post curing	UV light, 385 or 405 nm w/post curing	UV light, 385 or 405 nm w/post curing	***Same***
Equipment	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	***Same***
Performance Testing	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	ISO 4049:2013 ISO 10477:2018	***Same***
Flexural Strength	≥ 100 MPa	≥ 100 MPa	≥ 100 MPa	***Same***
Biocompatibility	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-17:2002 ISO 10993-18:2020 ISO 10993-23:2021 ISO/TS 21726:2019	ISO 7405:2018 ISO 10993-1:2018	ISO 10993-1:2018	***Similar***

The Technological Characteristics of the Subject and Predicate devices are the Same, Similar or Highly Similar.

Product Code/Regulation Number/Regulatory Class – The Subject and Predicate devices are the same.

Intended Use - The Subject and Predicate devices are Highly Similar in their intended use, differing only in reference to the device name. The Subject and Reference devices are Similar in their intended use, with the wording of the Subject device simplified to be inclusive of both permanent and temporary dental restorations through a general reference of "dental restorations".

Material/Chemical Composition - The Subject, Predicate and Reference devices are Same as they are all methacrylate-based polymer resins. Slight differences in chemical composition do not change the intended use of the Subject and Predicate devices to be used in the fabrication of dental restorations. The Subject device has demonstrated suitability for intended use through material non-clinical performance testing.

Rx/Sterility/Shades – The Subject, Predicate and Reference devices are the same.

Polymerization (Curing) Method - The Subject and Predicate devices are the Same. The Subject and Reference devices are the Same.

Equipment – The Subject, Predicate and Reference devices are the same as they have all been validated to work with compatible 3D printers and post-curing equipment.

Flexural Strength – The Subject, Predicate and Reference devices are the same with measured Flexural Strength values in excess of 100 MPa.

Performance Testing - The Subject and Predicate devices were tested to and met the requirements of the same material performance standards.

Biocompatibility - The Subject and Predicate devices are similar in the standards and biological endpoints the devices were evaluated to. Slight differences in the standards and tested endpoints do not change the intended use of the Subject and Predicate devices. Biocompatibility of the sponsor's Reference device is leveraged for the Subject device. Confirmatory cytotoxicity testing to ISO 10993-5, sensitization testing to ISO 10993-10, and irritation testing to ISO 10993-23 was performed on the Subject device.

Technological differences between the Subject and Predicate devices have been evaluated through non-clinical performance testing. The results of the tests performed show that the Subject device meets the requirements mentioned in the applicable standards and confirm that the Subject device performs similarly to Predicate device.

CLINICAL AND ANIMAL TESTING

The performance of methacrylate-based polymer resins in the clinical environment has been well established. No clinical or animal testing data is included in this submission.

NON-CLINICAL PERFORMANCE TESTING

Validation of the manufacturing process and compatible equipment was performed demonstrating consistency of the process output with that of the process input.

Physical property testing was performed on the Subject device to ISO 4049:2019, *Dentistry — Polymer-based restorative materials,* ISO 10477:2020, *Dentistry – Polymer-based crown and veneering materials.* Confirmatory testing was performed to ISO 22112:2017, *Dentistry – Artificial teeth for dental prostheses*. In most cases, results demonstrated the Subject device meets the property requirements of the referenced standards. Where performance test results did not meet the standard requirements, comparative testing was performed with the K201668 Reference device to support substantial equivalence.

A biological evaluation was performed on the Subject device according to ISO 10993-1. Biocompatibility testing was leveraged from the sponsor's K201668 Reference device. A comparative chemical characterization and toxicological assessment with the K201668 Reference device was performed to ISO 10993-18 with a risk assessment performed according to ISO 10993-17 and ISO/TS 21726. Confirmatory cytotoxicity testing was performed on the Subject device according to ISO 10993-5:2009.

An MRI safety assessment was performed on the Subject device to support MR Safety labeling as required by the FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*".

Non-clinical performance testing of the Subject device met the acceptance criteria for each validation and test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use.

CONCLUSION

Overall, the Indications for Use statements for the Subject and Predicate devices are the same differing only in device name and slightly in use duration. Overall, the Technological Characteristics of the Subject device are the same or highly similar to the Predicate device with any differences mitigated through non-clinical performance testing.

Overall, these similarities between the Subject and Predicate devices support a determination of substantial equivalence.