June 23, 2020

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: K201668
Trade/Device Name: VarseoSmile Crown Plus
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: June 18, 2020
Received: June 19, 2020

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,

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)*

K201668

Device Name

VarseoSmile Crown plus

Indications for Use *(Describe)*

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.

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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K201668

510(k) Summary
BEGO Bremer Goldschlägerei
Wilh. Herbst GmbH & Co. KG
VarseoSmile Crown plus
5/29/2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG Wilhelm-Herbst-Straße 1 28359 Bremen, Germany Telephone: +49 421-2028-394
Official Contact Email	Dr. Tanja Goetz - Regulatory Affairs Specialist regulatoryaffairsdental@bego.com
Representative/Consultant	Chris Brown, BSEE Aclivi, LLC 6455 Farley Road Pinckney, Michigan 48169 Telephone: +1 (810) 360-9773 E-mail: acliviconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	VarseoSmile Crown plus
Common Name:	Tooth shade resin material
Regulation Name:	Material, Tooth Shade, Resin
Regulation Number:	21 CFR 872.3690
Device Class:	Class II
Product Code:	EBF
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
K162537	CAD/CAMouflage Milling Block	Prismatik Dentalcraft, Inc.

510(k)	Reference Device Name	Company Name
K143033	Dentca Denture Base	Denterprise International, Inc.
K992645	Sinfony	ESPE Dental AG (3M)
K193553	VarseoSmile Temp	BEGO Bremer Goldschlägerei

INDICATIONS FOR USE

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.

DEVICE DESCRIPTION

VarseoSmile Crown plus is a light-cured, methacrylate-based resin used in 3D printers for the production of permanent crowns, inlays, onlays and veneers.

The Subject device is used by a dentist or dental technician for the CAD/CAM manufacturing of permanent dental restorations such as inlays, onlays, veneers and full crown prosthetics in compatible 3D-printers. Restorations fabricated using the Subject device are one-time use, permanent, prescription-only devices. VarseoSmile Crown ^{plus} is suitable for restoration of occlusal surfaces. VarseoSmile Crown ^{plus} is cured externally to the patient by light sources within a 3D printer and post-curing device.

The Subject device is a viscous solution consisting of methacrylate-based resins, dental glass-filler, photo initiators and pigments.

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.

EQUIVALENCE TO MARKETED DEVICE

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

Substantial Equivalence Comparison Table

Parameter	**Subject Device** VarseoSmile Crown plus BEGO Bremer Goldschlägerei	**Predicate Device** CAD/CAMouflage Milling Block (K162537) Prismatik Dentalcraft, Inc.	**Reference Device** Dentca Denture Base (K143033) Dentca, Inc.	**Reference Device** Sinfony (K992645) ESPE Dental AG (3M)	**Reference Device** VarseoSmile Temp (K193553) BEGO Bremer Goldschlägerei	**Substantial Equivalence with Predicate Device**
Product Code	EBF	EBF	EBI	EBF	EBG	***Substantially Equiv.***
Regulation Number	872.3690	872.3690	872.3760	872.3690	872.3770	***Substantially Equiv.***
Regulatory Class	Class II	Class II	Class II	Class II	Class II	***Substantially Equiv.***
Indication for Use	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.	CAD/CAMouflage Milling Block is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The CAD/CAMouflage Milling Block is made for fabricating temporary and permanent restorations such as inlays, onlays, veneers and full crown restorations.	Dentca Denture Base is a light-cured resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat cured and auto polymerizing resins. Fabrication of dental prosthetics with Dentca Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereolithographic additive printer, and curing light equipment.	Full veneering of crowns and bridges Complete crowns Inlays/onlays Fiber reinforced crowns and bridges Direct bonded bridges Telescopic and conical crowns Attachments and implant works Veneers Long term temporary restorations and their characterization Customization of acrylic and ceramic artificial teeth Extraoral repairs	VarseoSmile Temp resin is indicated for The fabrication of temporary dental restorations in conjunction with extraoral light-curing equipment.	***Very Similar (see below)***
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	Resin blank for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	Two-part, light- cured resin.	3D liquid (light-cured) print resin for dental CAD/CAM	***Very Similar (see below)***
Material	Methacrylate polymer resin (dimethacrylate)	Polymer resin	Methacrylate polymer resin (dimethacrylate)	Methacrylate polymer resin (dimethacrylate)	Methacrylate polymer resin (dimethacrylate)	***Very Similar (see below)***
Material Shades	Common VITA-shades	Common VITA-shades	Pink	Common VITA- shades	Common VITA-shades	***Substantially Equiv.***
Biocompatible	Yes	Yes	Yes	Yes	Yes	***Substantially Equiv.***
OTC or Rx	Rx	Rx	Rx	Rx	Rx	***Substantially Equiv.***
Sterile	Non-sterile	Non-sterile	Non-sterile	Non-Sterile	Non-sterile	***Substantially Equiv.***
Chemical Composition						
Chemical Composition	Methacrylate polymer resin with photo initiator, inhibitor and pigments	Polymer resin with fillers and pigments	Methacrylate polymer resin with photo initiator, inhibitor and pigments	Methacrylate polymer resin with photo initiator, inhibitor and pigments	Methacrylate polymer resin with photo initiator, inhibitor and pigments	***Very Similar (see below)***
Non-Clinical Performance Test Data						
Performance Testing	ISO 4049 ISO 10477	ISO 4049 ISO 10477	ISO 20795-1	Unknown	ISO 4049 ISO 10477	***Substantially Equiv.***
Flexural Strength ISO 4049 ≥100 MPa ISO 10477 ≥50 MPa	> 100 MPa	> 100 MPa	90.2 MPa	Unknown	> 100 MPa	***Substantially Equiv.***
Water Absorption ISO 4049 ≤40 µg/mm³ ISO 10477 ≤40 µg/mm³	< 40 µg/mm³	< 40 µg/mm³	14 µg/mm³	Unknown	< 40 µg/mm³	***Substantially Equiv.***
Water Solubility ISO 4049 ≤7.5 µg/mm³ ISO 10477 ≤7.5 µg/mm³	< 7.5 µg/mm³	< 7.5 µg/mm³	1.3 µg/mm³	Unknown	< 7.5 µg/mm³	***Substantially Equiv.***

In the above table, ***Substantially Equiv.*** is used to represent Substantially Equivalent.

Product Code/Regulation/Regulatory Class - The Subject and Predicate devices are Substantially Equivalent. The Dentca (K143033) and BEGO (K193554) Reference devices has a different Product Code and Regulation number due to different indications. The Subject and Sinfony (K992645) Reference devices share the same Product Code and Regulation name.

Indications for Use - The Subject and Predicate are Very Similar, differing only by reference to the device name and the Predicate device is also indicated for temporary restorations. Like the Subject device, the Dentca (K143033) Reference device is also indicated for fabricating permanent-use dental CAD/CAM restorative prosthetics. The Sinfony (K992645) Reference device shares common permanent restoration indications. The BEGO (K193553) Reference device is similar in that it is indicated for temporary dental restorations.

Technology - The Subject and Predicate devices are Very Similar in they are both resins for creation of restorations using CAD/CAM technology. The Predicate device (K162537) is offered in a different "working" form factor as it is a previously-cured resin and formed into a solid blank before use. The Predicate device is modified from a solid blank to final form (crown, inlay, onlay, veneer) through subtractive manufacturing CAD/CAM technology. The Subject device and Dentca (K143033) and BEGO (K193553) Reference devices use the same 3D printing CAD/CAM technology to cure the Subject device resin into final form demonstrating that additive manufacturing technology is viable for fabricating dental prosthetic devices. Differences between the Subject, Predicate and Sinfony Reference devices in the methods used to fabricate restorations (additive vs subtractive vs manual) do not change the intended use of the devices to create permanent dental restorations.

Material/Chemical Composition - The Subject and Predicate devices are Very Similar in they are both polymer resins. Slight differences in chemical composition do not change the intended use of the Subject, Predicate and Reference devices to be used in the fabrication of dental prostheses.

Material Shades - The Subject and Predicate devices are substantially equivalent.

The Subject, Predicate and Reference devices are all cured-resin materials indicated for the fabrication and/or repair of dental prosthetic devices. The Subject, Predicate and Dentca and BEGO Reference devices accomplish this by means of CAD/CAM technology. Minor differences in material properties or manufacturing process do not alter or impact the ability of the Subject device to be used for its intended use. In all cases, the Subject, Predicate and Reference devices have been demonstrated to be suitable for their intended use through non-clinical performance testing.

Overall, the Technological Characteristics of the Subject device and that of the Predicate and Reference devices support a finding of Substantial Equivalence.

CLINICAL TESTING

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

NON-CLINICAL PERFORMANCE TESTING

Validation of the manufacturing process 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 4049:2009, *Dentistry — Polymer-based restorative materials* and ISO 10477:2018, *Dentistry – Polymer-based crown and veneering materials*. Results demonstrated the Subject device meets the property requirements of the referenced standards.

The Subject device was evaluated for biocompatibility by way of the BEGO (K193533) Reference device.

CONCLUSION

Overall, the Subject device has the following similarities to the legally marketed Predicate device:

- Have nearly identical Indications for Use and Intended Use
- Have very similar Technological Characteristics
- Differences in Technological Characteristics with the Predicate device have been found to be substantially equivalent to the Technological Characteristics of the Reference devices.
- Any differences have been mitigated by demonstration of the Subject device to be suitable for intended use through additional non-clinical performance testing.

This satisfies the requirements of Decisions 1-5b of the Appendix A. Decision-Making flowchart in the FDA Guidance *Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*.

Overall, the Subject and Predicate devices have been demonstrated to be Substantially Equivalent.