September 23, 2022

DETAX GmbH
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222877
Trade/Device Name: FREEPRINT crown
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: August 5, 2022
Received: September 22, 2022

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, 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)*

K222877

Device Name
FREEPRINT® crown

Indications for Use *(Describe)*
FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.

The FREEPRINT® crown material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations.

Fabrication of FREEPRINT® crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

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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510(k) Summary
DETAX GmbH
FREEPRINT® crown
9/13/2022

ADMINISTRATIVE INFORMATION

Manufacturer Name:	DETAX GmbH Carl-Zeiss-Strasse 4 D-76275 Ettingen, Germany Telephone: +49 7243/510-138	Consultant:	Aclivi, LLC 3250 Brackley Drive Ann Arbor, Michigan 48105 Telephone: +1 810 360-9773
Official Contact: Email:	Markus Stratmann - Divisional Director 3D Markus.Stratmann@detax.de		Chris Brown - Manager acliviconsulting@gmail.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	FREEPRINT® crown
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
K202846	TERA HARZ	Graphy Inc

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

INDICATIONS FOR USE

FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.

The FREEPRINT® crown material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations.

Fabrication of FREEPRINT® crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

DEVICE DESCRIPTION

The Subject device is a light-cured methacrylate-based resin used in 3D printers for the production of temporary or permanent 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 dental restorations.

Restorations fabricated using the Subject device are one-time use, prescription-only devices. The Subject device is a viscous solution consisting of methacrylate-based resins, 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.

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 FREEPRINT® crown DETAX GmbH	*FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.* *The FREEPRINT® crown material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations.* *Fabrication of FREEPRINT® crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.*
Predicate Device TERA HARZ (K202846) Graphy Inc	*TERA HARZ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.* *The TERA HARZ material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations.* *Fabrication of TERA HARZ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.*
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 by 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 FREEPRINT® crown DETAX GmbH	Predicate Device TERA HARZ (K202846) Graphy Inc	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, Technological Characteristics	Comparative Bench Performance Testing	***Same***
Product Code	EBF	EBF, EBG	EBF	***Same***
Regulation Number	872.3690	872.3690	872.3690	***Same***
Regulatory Class	Class II	Class II	Class II	***Same***
Intended Use	FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The FREEPRINT® crown material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of FREEPRINT® crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.	TERA HARZ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The TERA HARZ material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of TERA HARZ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.	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.	***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	Methacrylate polymer resin (includes dimethacrylate)	Methacrylate polymer resin (dimethacrylate)	Methacrylate polymer resin (dimethacrylate)	***Highly Similar***
Material Shades	Common VITA-shades: A1, A2, A3, B1, B3, C3, D3, BL	Common VITA-shades	Common VITA-shades	***Highly Similar***
Biocompatible	Yes	Yes	Yes	***Same***
OTC or Rx	Rx	Rx	Rx	***Same***
Sterile	Non-sterile	Non-sterile	Non-sterile	***Same***
Shelf-Life	2 years	Not defined	Not defined	***Not applicable***
Chemical Composition	Methacrylate polymer resin with photo initiator, and pigments	Polyurethane Resin; Methacrylate; Dimethacrylate; Phosphine oxide; Butylated hydroxytoluene; and Pigments	(Meth)acrylate-based resin with photo initiator and pigments	***Highly Similar***
Polymerization (Curing) Method	Visible light, 385 nm w/post curing	UV light, 405~412nm w/post curing	UV light, 405 nm w/post curing	***Highly Similar***
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 4049:2013 ISO 10477:2018	ISO 4049:2013 ISO 10477:2018	***Highly Similar***
Depth of Cure	Hardness of bottom surface ≥70% top surface	Not defined	Not defined	***Highly Similar (meets requirements of ISO 4049 and ISO 10477)***
Surface Finish	Glossy surface after polishing	Not defined	Not defined	***Highly Similar (meets requirements of ISO 4049 and ISO 10477)***
Flexural Strength	≥ 100 MPa	Avg. 148.73 MPa	≥ 100 MPa	***Highly Similar (meets requirements of ISO 4049 and ISO 10477)***
Water Sorption	≤ 40 µg/mm3	Avg. 13.03 µg/mm3	≤ 40 µg/mm3	***Highly Similar (meets requirements of ISO 4049 and ISO 10477)***
Water Solubility	≤ 7.5 µg/mm3	Avg. 1.00 µg/mm3	≤ 7.5 µg/mm3	***Highly Similar (meets requirements of ISO 4049 and ISO 10477)***
Biocompatibility Testing	ISO 7405:2018 ISO 10993-1:2018 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-11:2017 ISO 10993-17:2002 ISO 10993-18:2020 ISO 10993-23:2021 ISO/TS 21726:2019	ISO 7405:2014 ISO 10993-1:2018 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-6:2016 ISO 10993-10:2013 ISO 10993-11:2017	Tested Standards not listed in 510(k) Summary document.	***Highly Similar***

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

Intended Use - The Subject and Predicate devices are same Highly Similar in their intended use, differing only in reference to the device name.

Material/Chemical Composition - The Subject and Predicate devices are same Highly Similar in they are both methacrylate 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 permanent or temporary dental prostheses. The materials are an alternative to traditional heat cured and auto polymerization resins.

The Subject device has demonstrated suitability for intended use through material non-clinical performance testing.

Polymerization (Curing) Method - The Subject and Predicate devices are same Highly Similar in they are both light-cured polymer resins. Slight differences in the curing light wavelength does not change the intended use of the Subject and Predicate devices to be used in the fabrication of dental prostheses.

Performance Testing - The material performance standards used for testing the Subject and Predicate devices are highly similar, differing only in release date of the documents. The Subject device was tested to the most recent versions of ISO 4049 and ISO 10477. The material performance requirements of both standards did not change in the new release dates of each document. The Subject, Predicate and Reference devices all meet the material performance requirements of both the ISO 4049 and ISO 10477 documents.

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.

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

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* and ISO 10477:2018, *Dentistry – Polymer-based crown and veneering materials*. Results

demonstrated the Subject device meets the property requirements of the referenced standards. Comparative material property testing was performed with the Reference device demonstrating similar performance.

A biological evaluation was performed on the Subject device. Chemical characterization was performed to ISO 10993-18 with a risk assessment performed according to ISO 10993-17 and ISO/TS 21726. Biocompatibility testing was performed on the Subject device according to ISO 10993-1:2018 and ISO 7405:2014 according to the standards listed in the Technological Characteristics comparison table above.

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 highly similar 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.