July 15, 2021

Graphy Inc.
% Peter Chung
Representative
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K202846
Trade/Device Name: TERA HARZ
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: June 22, 2021
Received: June 23, 2021

Dear Peter Chung:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202846

Device Name
TERA HARZ

Indications for Use *(Describe)*
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.

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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Graphy

510(k) Summary
For
TERA HARZ
K202846

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

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Office Phone: 82-2-864-3056
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Contact Person: Mr. Tae-woo Kim, QMR

II. SUBMISSION CORRESPONDENT

Plus Global
300, Atwood Street, Pittsburgh, PA, 15213, USA

Office Phone: 412-687-3976

Contact: Mr. Peter Chung, Representative
Email: peterchung210@gmail.com

III. DATE PREPARED

July 12, 2021

IV. DEVICE

Trade or Proprietary Name:	TERA HARZ
Common or Usual Name:	Preformed Crown and Bridge
Classification Name:	Tooth shade resin material (21 CFR 872.3690)
	Crown and Bridge, Temporary, Resin (21 CFR 872.3770)
Regulatory Class:	II
Product Code:	EBF, EBG
Classification Panel:	Dental

V. PREDICATE DEVICE

Primary Predicate Device:
K201668, Tooth shade resin material / BEGO Bremer Goldschlägerei Wilh. Herbst GmbH

& Co. KG

Reference device:
K193553, Temporary Crown and Bridge Resin / BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG

VI. DEVICE DESCRIPTION

The TERA HARZ is a light-cured, methacrylate oligomer based polymerizable resin used by dentist or dental technician for the CAD/CAM manufacturing of indirect restorative for both anterior and posterior restorations, including occlusal surfaces, such as temporary or permanent crowns and bridges, inlays, onlays and veneers. Methacrylate based resin is known materials, commonly used in the dental industry for fixed and removable prosthetic devices due to their physical-chemical, mechanical and biocompatible properties.

The TERA HARZ is made by Methacrylate-based resins. It has stored in a black 1,000g of HDPE bottle. It contains materials with shade A1/A2/A3. This resin is a liquid photopolymer material that is polymerized by UV laser at 405~412nm. the resin can be used to create a customized artificial permanent tooth model with a 3d printer that is cured by ultraviolet light. The liquid UV curing resin is cured at a specific wavelength (395~405nm) by the photo-initiator contained in the resin. Curing in a 3D printer is related to the conditions of the printer equipment, and is typically 100µm in layer thickness, and is output at a resolution of 40 to 90µm on the x, y axis. This device should use specific 3D Printer equipment using UV light source, and it is possible to produce three-dimensional printed matter by curing lamination step by step a thickness of 100µm.
However, scanner, design software, 3D printer and post-cure unit are not included with the device.

TERA HARZ can be used in combination with specified lasers and DLP based 3D printers which support dental materials. TERA HARZ is a resin for the generative production of permanent or temporary dental restorations based on image projection systems (405-412 nm). The formulation of TERA HARZ is optimized for the requirements of a robust production guaranteeing constant high quality. The TERA HARZ is successfully tested for biocompatibility, certainly meets all mechanical and application demands. The material is used in a 3D printer, which prints the shape determined by a 3D stereo-lithographic drawing.
The material can be used for build processes with layer thicknesses from 25 up to 100 µm. After printing, the printed product is recommended to use a UV-light curing for final polymerization.

3D printer is not included with the device.

These fabrications of TERA HARZ are beginning with the dental clinician prescribing indirect restorative to treat a patient's both anterior and posterior restorations, including occlusal surfaces, and decision to use methacrylate-based resins is made by the dental clinician. TERA HARZ, a permanent or temporary restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations, is manufactured in a 3D printer that is compatible.

The dental clinician can generate a digital file by scanning the patient's mouth directly using approved Intraoral scanner software. This digital file is a series of CAD files (.stl) for building models that can be used to fabricate permanent or temporary restorations. Commonly used standard dental software is used by dental professionals to virtually design a restoration and generate an industry-standard "STL" 3D dataset which reflects the intended shape and contour. The design software used is 3D Scanner by 3Shape A/S (510(K) Exempt). The specialized prosthetic treatment planning software has a establishment registration for the intended use under FDA Classification Product Code NOF, regulation 872.3661. This software is used for management of 3D scanned prosthetic models, prosthetic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned prosthetic models, virtual planning of prosthetic treatments by simulating tooth movements, and design of permanent or temporary restorations based on 3D scanned prosthetic models.

Once dental clinic manufacturing unit receive the data that *.stl CAD files of crown and bridge the 3D printer begins additive manufacturing. The dental clinician (e.g., dentist) generates sequential 3D printed models replicating the approved treatment plan. The permanent or temporary restorations is 3D printed and cured in a post-curing unit. The fabricated permanent or temporary restorations are cut to fit dentition, the cleaned and polished to remove rough edges by the dental clinician. The prescribing physician review and approves the permanent or temporary restorations are provides them to the patient the confirming fit and design.

VII. INDICATION FOR USE

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 permanent or temporary 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.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table compares the TERA HARZ to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

	Primary PREDICATE Device (K201668)	**REFERENCE Device (K193553)**	**SUBJECT Device (K202846)**	**Discussion**
Manufacturer	**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**	**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**	**Graphy Inc.**	—
Trade Name	VarseoSmile Crown Plus	VarseoSmile Temp	TERA HARZ	—
Regulation Description	Tooth shade resin material	Temporary Crown and Bridge Resin	Temporary Crown, Bridge Resin and Tooth Shade	No difference.
Regulation Number	21 CFR 872.3690	21 CFR 872.3770	21 CFR 872.3770 21 CFR 872.3690	No difference.
Product Code	EBF	EBG	EBG, EBF	No difference.
Class	II	II	II	No difference.
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.	VarseoSmile Temp resin is indicated for the fabrication of temporary dental restorations in conjunction with extraoral light-curing equipment.	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.	Similarities: Indication for use of the subject device is slightly different from the primary predicate in phrase but fundamental indication is the identical.
Manufacturing Technology	3D liquid (light-cured) print resin for dental	3D liquid (light-cured) print resin for dental	3D liquid (light-cured) print resin for dental	No difference.

	Primary PREDICATE Device (K201668)	REFERENCE Device (K193553)	SUBJECT Device (K202846)	Discussion
Manufacturer	**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**	**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**	**Graphy Inc.**	—
	CAD/CAM	CAD/CAM	CAD/CAM	
Material	Methacrylate polymer resin (dimethacrylate)	Methacrylate polymer resin (dimethacrylate)	Methacrylate polymer resin (dimethacrylate)	No difference.
Material Shades	Common VITA-shades	Common VITA-shades	Common VITA-shades	No difference.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.
OTC or Rx	Rx	Rx	Rx	No difference.
Sterile	Non-sterile	Non-sterile	Non-sterile	No difference.
Chemical Composition	Methacrylate polymer resin with photo initiator, inhibitor and pigments	Methacrylate polymer resin with photo initiator, inhibitor and pigments	Polyurethane Resin; Methacrylate; Dimethacrylate; Phosphine oxide; Butylated hydroxytoluene; and Pigments	Similarities: The subject and predicate or reference devices are very similarities in they are all 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. The material is an alternative to traditional heat cured and auto polymerization resins.
Flexural Strength (≥100 MPa; ISO 4049, ≥50 MPa; ISO 10477)	≥100 MPa	≥100 MPa	Avg. 148.73 MPa	Similarities: the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns. Both devices meet requirements from ISO 4049:2019 and ISO 14077:2018.
Water sorption (≤40 µg/mm³)	≤40 µg/mm³	≤40 µg/mm³	Avg. 13.03 µg/mm³	Similarities: the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns. Both devices meet

	Primary PREDICATE Device (K201668)	REFERENCE Device (K193553)	SUBJECT Device (K202846)	Discussion
Manufacturer	**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**	**BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG**	**Graphy Inc.**	—
				requirements from ISO 4049:2019 and ISO 14077:2018.
Solubility (≤7.5 µg/mm³)	≤7.5 µg/mm³	≤7.5 µg/mm³	Avg. 1.00 µg/mm³	Similarities: the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns. Both devices meet requirements from ISO 4049:2019 and ISO 14077:2018.

IX. NON-CLINICAL PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Manufacturing Validation

A manufacturing validation was performed to demonstrate the manufacturing process for TERA HARZ.

An independent 3rd party software and digital calipers were used to perform point-to-point and critical displacement measurement.

All translational measurements were within 0.150 mm of the target input value, the predefined tolerance of the manufacturing process. There were no statistical differences in the difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria.

And the test also conducted studies on the effect of manufacturing validation and material reuse on the properties of the final finished device according to FDA's published guidance documents, "Technical Considerations for Additive Manufactured Medical Devices".

The TERA HARZ were outputted by each different output condition and each flexural strength were measured and the evaluation criteria of the all the specimens were more than 50 MPa. The optimal output condition is that the output angle is 0°, and the output position is centered to confirming that the optimal condition is to be output.

In addition, it was confirmed that there was no problem in the number of effective outputs for repeated material output up to 7 times.

Performance Testing

The predicate/reference devices performed tests for Flexural Strength, Flexural Modulus, Water Solubility, Water Sorption, and Biocompatibility content. The predicate/reference devices performed these tests as well and all met the requirements of ISO 4049:2013, Dentistry – Polymer-based restorative materials, and ISO 10477:2018, Dentistry – Polymer-based crown and veneering materials.

Biocompatibility

A biocompatibility discussion was conducted. The TERA HARZ uses the Dimethacrylate-based resins and this material has been tested and shown to be compliant with the following standards:

- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-6:2016, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

X. CLINICAL DATA

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

XI. CONCLUSIONS

The TERA HARZ is very similar to both predicate devices and demonstrate substantial equivalence to predicate/reference devices K201668 and K193553.

An analysis for subject device compared to the predicate device show TERA HARZ and the Resin for Temporary Crown & Bridge meet all two devices share the same product code, meet the requirements, and all two are biocompatible.

In addition, an analysis for subject device compared to the predicate device show TERA HARZ and the Resin for Temporary Crown & Bridge meet the requirements of ISO 10477:2018, Dentistry – Polymer-based crown and veneering materials and ISO 4049:2013, Dentistry – Polymer-based restorative materials. All two devices meet or

exceed the minimum strength requirements, and all two are biocompatible.

Any differences between subject device and the predicate devices are minimal and present no new risks.