November 1, 2023

Graphy Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K233502
Trade/Device Name: Tera Harz II
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: October 30, 2023
Received: October 31, 2023

Dear Dave Yungvirt:

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
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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)*

Device Name
TERA HARZ II

Indications for Use *(Describe)*
TERA HARZ II is intended as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.
The TERA HARZ II 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 II requires a computer-aided and manufacturing (CAD/CAM) system that includes the following : scanner, design software, additive printer, and post-cure unit.

	Brand	Type
Design :	3 Shape A/S	TRIOS 3 Basic
Instraoral scanner	3 Shape A/S	3Shape dental system
Design software		
Additive Manufacturing system :		
3D Printer	UNIZ	NBEE
	SprintRay Inc.	Pro 95
Post-Curing :		
Post-cure unit	CureM	U102H
	TERA HARZ CURE	THC

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 II

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

Graphy Inc.
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Office Phone: +82-2-864-3056
Fax: 82-2-864-3057
Contact Person: Mr. Moon-Soo Park, Assistant Manager of RA Team

II. SUBMISSION CORRESPONDENT

III. DATE PREPARED

04 October 2023

IV. DEVICE

Trade or Proprietary Name:	TERA HARZ II
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:
K202846, TERA HARZ / Graphy Inc. (Class II)
Referencee Device
K222414, TERA HARZ DENTURE / Graphy Inc. (Class II)

VI. DEVICE DESCRIPTION

The TERA HARZ II is a light-cured, methacylate 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 dcclusal surfaces, such as temporary or permanent crowns and bridges, inlays, onlays, and veneers. Methacrylate based resin is well 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 II 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/B1/B2/B3/C1/C2/C3/D1/D2/D3/OM1/OM2/OM3/M4. 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 II can be used in combination with all lasers and DLP based 3D printers which support dental materials. TERA HARZ II is a resin for the generative production of long-term temporary dental restorations based on image projection systems (405-412 nm). The formulation of TERA HARZ II is optimized for the requirements of a robust production guaranteeing constant high quality. The TERA HARZ II 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.

These fabrications of TERA HARZ II 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 II, 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 II is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces.

The TERA HARZ II 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 II requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.

	Brand	**Type**
Design:		
Intraoral scanner	3Shape A/S	TRIOS 3 Basic
Design software	3Shape A/S	3Shape Dental System
Additive Manufacturing System:		
3D Printer	UNIZ SprintRay Inc.	Nbee SprintRay Pro 95
Post-Curing:		
Post-cure unit	CureM TERA HARZ CURE	U102H THC2

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The indications for use and mechanism of action of subject device is identical to the predicate device and supports a determination of substantial equivalence.

However, there two main differences in the predicate device because the material of use and the physical property values are differed. The subject device has more flexible physical properties compared to the predicate device.

So, TERA HARZ DENTURE is selected as a reference device to support difference of raw material. The reference device has exactly the same raw material composition as the subject device. In addition, although there is a difference in physical property values, both products satisfy the acceptance criteria of ISO 10477:2020.

The following table compares the TERA HARZ II to the predicate device with respect to indications for use, principles of operation, technological characteristics, method of manufacturing.

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. Any differences in technology characteristics are accompanied by information that demonstrated the device is as safe and as effective as the predicate device and do not raise different questions of safety and effectiveness than the predicate.

It was concluded, therefore, that the technological differences do not raise different questions of safety and effectiveness

	SUBJECT Device	Primary PREDICATE Device (K202846)	Significant Difference
Manufacturer	**Graphy Inc.**	**Graphy Inc.**	–
Trade Name	TERA HARZ II	TERA HARZ	

Regulation Description	-Tooth shade resin materials - Crown and Bridge, Temporary, Resin	-Tooth shade resin materials - Crown and Bridge, Temporary, Resin	**Same**
Regulation Number	-21 CFR 872.3690 -21 CFR 872.3770	-21 CFR 872.3690 -21 CFR 872.3770	**Same** e
Product Code	EBF EBG	EBF EBG	**Same**
Class	II	II	**Same**
Indication for Use	TERA HARZ II 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.	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.	**Similar:** The indication for use of the subject device is very similar to the predicate device.
Mechanism of Action	The product is a photopolymer liquid resin that is manufactured to produce an output within UV lighting 3D printer. The material is for producing polymeric dental prosthesis according to ISO 10477, type 2 and class 2. Using a DLP or SLA 3D printer that uses photopolymer materials, it is produced 3D output layer by layer. By reading a STL file which contains 3D information of the dental prosthesis of a patient's oral cavity, the 3D printer can create a virtual layer to form a	The product is a photopolymer liquid resin that is manufactured to produce an output within UV lighting 3D printer. The material is for producing polymeric dental prosthesis according to ISO 10477, type 2 and class 2. Using a DLP or SLA 3D printer that uses photopolymer materials, it is produced 3D output layer by layer. By reading a STL file which contains 3D information of the dental prosthesis of a patient's oral cavity, the 3D printer can create a virtual layer to form a	**Same**

	SUBJECT Device	Primary PREDICATE Device (K202846)	Significant Difference
Manufacturer	**Graphy Inc.**	**Graphy Inc.**	–
Trade Name	TERA HARZ II	TERA HARZ	
	continuous layer. When the 3D printer emits light to the resin with specific pattern of a shape, the photoinitiator in the resin absorbs the pattern of UV wavelength band. It causes a photocuring reaction in a pattern shape and the photopolymer resin is curedlayer by layer and it is continuously carried out to produce the shape that you want. The operation is carried out continuously and finally the output are produced.	continuous layer. When the 3D printer emits light to the resin with specific pattern of a shape, the photoinitiator in the resin absorbs the pattern of UV wavelength band. It causes a photocuring reaction in a pattern shape and the photopolymer resin is curedlayer by layer and it is continuously carried out to produce the shape that you want. The operation is carried out continuously and finally the output are produced.	
Manufacturing Technology	Additive	Additive	**Same**
Material of Use	Methacrylate-based resins with photo-initiator, inhibitor and pigments	Methacrylate polymer resin (dimethacrylate)	**Different** : the subject device differs from the predicate device in the material of use. The two products are similar methacrylate-based resins, but they differ slightly in raw material composition. .
Product state	Pre-mixed resin(liquid)	Pre-mixed resin(liquid)	**Same**
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	**Same**
Performance Testing	ISO 10477:2020	ISO 10477:2020	**Same** : the subject device and predicate device have same performance testing standard
Depth of Cure (%) (Bottom surface shall be not less than 70% of the hardness of top surface)	Avg. 91.3	Avg. 93.5	**Similar** : the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns.
Flexural Strength (≥50 MPa; ISO 10477)	Avg. 125.5	Avg. 148.73	**Similar** : the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns.
Water sorption (≤40µg/mm3)	Avg. 22.03	Avg. 13.03	**Similar** : the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns.
Solubility (≤7.5 µg/mm3)	Avg. 0.12	Avg. 1.00	**Similar** : the specifications are in the same range. This minor variance does not introduce additional safety or

	SUBJECT Device	Primary PREDICATE Device (K202846)	Significant Difference
Manufacturer	**Graphy Inc.**	**Graphy Inc.**	**–**
Trade Name	TERA HARZ II	TERA HARZ	

			efficacy concerns.
Shade consistency	The difference in color from different batches was not observed.	The difference in color from different batches was not observed.	**same**
Color stability	Any color change after aging treatments was not detected.	Any color change after aging treatments was not detected.	**same**
OTX or Rx	Rx	Rx	**Same**
Sterile	non-sterile	non-sterile	**Same**
Shelf-life	2 year	2 year	**Same**

	SUBJECT Device	REFERENCE Device (K222414)	Significant Difference
Manufacturer	**Graphy Inc.**	**Graphy Inc.**	–
Trade Name	TERA HARZ II	TERA HARZ DENTURE	

Regulation Description	-Tooth shade resin materials - Crown and Bridge, Temporary, Resin	-resin, denture, relining, repairing, rebasing	**Different**
Regulation Number	-21 CFR 872.3690 -21 CFR 872.3770	-21 CFR 872.3760	**Different**
Product Code	EBF EBG	EBI	**Different**
Class	II	II	**Same**
Indication for Use	TERA HARZ II 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.	The TERA HARZ DENTURE is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with the TERA HARZ DENTURE requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on digital impression, stereolithographic additive printer, and curing light equipment.	**Different:** The indication for use of the subject device is different from the reference device.
Mechanism of Action	The product is a photopolymer liquid resin that is manufactured to produce an output within UV lighting 3D printer. The material is for producing polymeric dental prosthesis according to ISO 10477, type 2 and class 2. Using a DLP or SLA 3D printer that uses photopolymer materials, it is produced 3D output layer by layer. By reading a STL file which contains 3D information of the dental prosthesis of a patient's oral cavity, the 3D printer can create a virtual layer to form a	Denture Base Resin is used to fabricated synthetic substances that form denture base after polymerization. The denture base is the part of a denture that rests on the foundation tissues and to which teeth are attached.	**Different**

	SUBJECT Device	REFERENCE Device (K222414)	Significant Difference
Manufacturer	**Graphy Inc.**	**Graphy Inc.**	–
Trade Name	TERA HARZ II	TERA HARZ DENTURE	

	continuous layer. When the 3D printer emits light to the resin with specific pattern of a shape, the photoinitiator in the resin absorbs the pattern of UV wavelength band. It causes a photocuring reaction in a pattern shape and the photopolymer resin is curedlayer by layer and it is continuously carried out to produce the shape that you want. The operation is carried out continuously and finally the output are produced.		
Manufacturing Technology	Additive	Additive	**Same**
Material of Use	Methacrylate-based resins with photo-initiator, inhibitor and pigments	Methacrylate-based resins with photo-initiator, inhibitor and pigments	**Same** : The subject device and the reference device have the same raw material.
Product state	Pre-mixed resin(liquid)	Pre-mixed resin(liquid)	**Same**
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	**Same**
Performance Testing	ISO 10477:2020	ISO 20795-1:2013	**Different :** The subject device and the reference device applied different technical standards.
OTX or Rx	Rx	Rx	**Same**
Sterile	non-sterile	non-sterile	**Same**
Shelf-life	2 year	2 year	**Same**

IX. PERFORMANCE DATA

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

Manufacturing Validation

A manufacturing validation was performed to demonstrate themanufacturing process for TERA HARZ II

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 II is 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 6 times.

Performance Testing

The predicate devices performed tests for Depth of Cure, Flexural Strength, Water Solubility, Water Sorption, and Biocompatibility content. The predicate/reference devices performed these tests as well and all met the requirements of ISO 10477:2020, Dentistry – Polymer-based crown and veneering materials.

Comparison Performance Testing

Bench testing was performed on both the subject device and the predicate device (K202846) to evaluate critical properties including Flexural strength, Shaede consistency and Color stability, Water sorption,solubility, and depth of cure. All met the requirements of ISO 10477:2020.

Biocompatibility

Biocompatibility Tests in accordance with the FDA Guidance Document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1 : Evaluation and Testing within a risk management process".

The subject device is considered a surface device that is contact with the mucosal

membrane for > 30 days. The ISO 10993-1 standard was followed the following biological safety aspects have been addressed:

- 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

Clinical performance data was not provided for TERA HARZ II.

XI. CONCLUSIONS

The TERA HARZ II is very similar to the predicate device and demonstrate substantial equivalence to predicate device, K202846.

An analysis for subject device compared to the predicate device show TERA HARZ II and the TERA HARZ ll meet the requirements of Manufacturing Validation, 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 II and the TERA HARZ meet the requirements of ISO 10477:2020, Polymer-based crown and veneering materials All two devices meet or exceed the minimum strength requirements, and all two are biocompatible.

Any differences between subject device and the predicate device are material of use and value of physical properties . So reference device, which has same composition of raw materials, is added to support material of use. Also two products meet the requirements of ISO 10477:2020.

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