August 11, 2022

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

Re: K222414
Trade/Device Name: Tera Harz Denture
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI
Dated: August 2, 2022
Received: August 10, 2022

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, 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)*
K222414

Device Name
TERA HARZ DENTURE

Indications for Use *(Describe)*
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 a digital impression, digital light processing(DLP) printer, and curing light equipment.

| | Brand | Type |
|---|---|---|
| Intraoral scanner | 3Shape A/S | TRIOS 3 Basic |
| Model scanner | 3Shape A/S | E3 |
| Printing: | | |
| 3D Printer | UNIZ | SLASH 2 |
| | SprintRay Inc. | SprintRay Pro 95 |
| Post-Curing: | | |
| Post-cure unit | CureM | U102H |

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary For TERA HARZ DENTURE

# [Complying with 21 CFR 807.92]

## I. SUBMISSION SPONSOR

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## II. SUBMISSION CORRESPONDENT

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## III. DATE PREPARED

March 10, 2022

## IV. DEVICE

| | |
|---|---|
| Trade or Proprietary Name: | TERA HARZ DENTURE |
| Common or Usual Name: | Denture Base Resin |
| Classification Name: | Denture relining, repairing, or rebasing resin. (872.3760) |
| Regulatory Class: | II |
| Product Code: | EBI |
| Classification Panel: | Dental |

## V. PREDICATE DEVICE

Primary Predicate Device:
K162044, Dentca Denture Base II / Dentca, Inc.

## VI. DEVICE DESCRIPTION

The TERA HARZ DENTURE is a light-cured, methacrylate-based resin commonly used in additive manufacturing when producing dental structures (both full and partial dentures).

Methacrylate-based resin is a known material that is often used in the dental industry for fixed and removable prosthetic devices due to its physical-chemical, mechanical, and biocompatible properties.

The TERA HARZ DENTURE is made from methacrylate-based resins. It is stored in a black 1,000g HDPE bottle. This resin is a liquid photopolymer material that is polymerized by a ultraviolet (UV) laser at 405~412 nm. The resin can be used to create customized removable full and partial dentures with a 3D printer cured by UV light. The UV curable liquid resin is cured at a specific wavelength (395~405 nm) by the photo-initiator contained in the resin. The process parameters of the 3D printer affect the quality of the 3D printed objects. The printer equipment should be set to a resolution of 40 to 90 µm on the x,y axis (horizontal resolution) and 100 µm on the z axis (vertical resolution). The TERA HARZ DENTURE should be used with a specific 3D printer that uses a UV light source and produces 3D printed objects with layer thickness of 100 µm.

The TERA HARZ DENTURE does not come with a scanner, design software, 3D printer, or post-cure unit.

The TERA HARZ DENTURE can be used to manufacture customized removable full and partial dentures using compatible equipment.

Digital file can be generated by scanning the patient's intraoral region directly with an intraoral scanner or by scanning the teeth model with a model scanner under the FDA Classification Product Code NOF, regulation 872.3661.

The digital file consists of a series of CAD files (.stl) for building 3D models that can be used to create the denture base. Specialized dental software is used to virtually design a denture base and generate an industry-standard “STL” 3D dataset which reflects the intended shape and contour. The design software used is 3Shape Dental System™ under the FDA Classification Product Code NOF, regulation 872.3661. This software is used to manage 3D scanned teeth models, as well as to measure, analyze, examine, and visualize 3D scanned teeth models to design denture models.

STL files are transferred to a 3D printer. Using the *.stl CAD file data, the 3D printer begins additive manufacturing, which is used to create customized 3D printed dentures. The 3D printed dentures are further cured in the post-curing device. Manufactured dentures are polished and washed accordingly.

Before giving the dentures to the patients, the dentist reviews them to ensure the optimal fit and design.

**Photographs**

Figure 1 – TERA HARZ DENTURE – Denture Base View

**Accessories for the Product, Integral Parts of Package**

Not applicable,

This device does not come with a compatible intraoral or model scanners, design software, 3D printers, post-cure unit, and other accessories used in fabrication.

## VII. INDICATION FOR USE

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.

## VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

To demonstrate safety and effectiveness of the TERA HARZ DENTURE and to show substantial equivalence to the predicate device, the following non-clinical tests were completed: Flexural Strength, Water sorption, and Solubility.

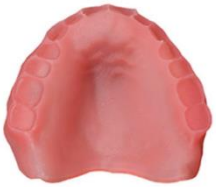
The result of the performance comparison test demonstrates that the TERA HARZ DENTURE is substantially equivalent to the predicate device. Potential minor variance does not introduce additional safety or efficacy concerns. Both devices meet requirements from ISO 20795-1:2013.

The performance characteristics of the TERA HARZ DENTURE are comparable to those of the predicate device for this particular indication and raise no questions on safety and effectiveness.

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

Therefore, it is concluded that the technological differences do not raise questions on safety and effectiveness.

| | SUBJECT Device | Primary PREDICATE Device | Significant Difference |
|---|---|---|---|
| Manufacturer | Graphy Inc. | Dentca, Inc. | - |
| Trade Name | TERA HARZ DENTURE | Dentca Denture Base II | - |
| 510(k) No. | - | K162044 | - |
| Regulation Description | Resin, Denture, Relining, Repairing, Rebasing | Resin, Denture, Relining, Repairing, Rebasing | No difference |
| Regulation Number | 21 CFR 872.3760 | 21 CFR 872.3760 | No difference |
| Product Code | EBI | EBI | No difference |
| Class | II | II | No difference |
| Indications for Use | 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. | The DENTCA Denture Base II 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 Dentca Denture Base II requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, stereolithographic additive printer, and curing light equipment. | No difference |
| Fabrication of Denture Base | Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber | Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber | No difference |
| Device Characteristics | Digital Scan file: STL<br>Design software: 3shape dental system (NOF)<br>Stereolithographic additive printer: SPRINTRAY PRO 95<br>Operation software: Rayware<br>Curing equipment: CUREM 102H (405nm) | Digital Scan file: STL<br>Design software: Dentca Pala Design Studio (NOF)<br>Stereolithographic additive printer: SPRINTRAY PRO 95<br>Operation software: Rayware<br>Curing equipment: Pro Cure (405nm) | The design software are not equivalent, but they are both registered on FDA with Product Code NOF.<br>Curing equipment are produced by different manufacturers, but share the same |

| | | | |
|---|---|---|---|
| | | | wavelengths of 405nm. |
| Device color | - Clear<br>- White<br>- Light pink<br>- Pink<br>- Dark pink<br>- Black pink | - Light pink<br>- Original pink<br>- Reddish pink<br>- Dark pink | - |
| Materials of Use | Methacrylate-based resins with photo-initiator, inhibitor and pigments | Methacrylate-based resins with photo-initiator, inhibitor and pigments | - |
| Product State | Pre-mixed resin (liquid) | Pre-mixed resin (liquid) | No difference |
| Design |  |  | No difference |
| Performance Testing | ISO 20795-1:2013<br>Requirements:<br>- Flexural strength > 65 MPa.<br>- Flexural modulus > 2,000 MPa.<br>- Water absorption ≤ 32 μg/mm³<br>- Water solubility ≤ 1.6 μg/mm³<br><br>Test Results:<br>- Average Flexural strength = 94.43 MPa<br>- Flexural modulus: Average 2545.32 MPa<br>- Average Water absorption=10.30 μg /mm³<br>- Average Water solubility =1.22 μg/mm³ | ISO 20795-1:2013<br>Requirements:<br>- Flexural strength> 65 MPa.<br>- Flexural modulus > 2,000 MPa.<br>- Water absorption ≤ 32 μg/mm³<br>- Water solubility ≤ 1.6 μg/mm³<br><br>Test Results:<br>- Average Flexural strength= 92.64 MPa<br>- Average Flexural modulus = 2362.58 MPa<br>- Average Water absorption = 10.34 μg /mm³<br>- Average Water solubility = 1.05 μg /mm³ | The SUBJECT Device has higher Flexural strength, Flexural modulus, and Water solubility than the Primary PREDICATE Device, but showed lower water absorption. There was no significant difference in their performance testing results between the two devices, and they all satisfied the required standards from ISO 20795-1:2013. |
| Biocompatibility | Biocompatible according to ISO 10993 | Biocompatible according to ISO 10993 | |
| Sterile | Non-sterile | Non-sterile | No difference |
| Shelf-life | 1 years | 2 years | - |

## IX. PERFORMANCE DATA

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

### Manufacturing Validation

A manufacturing validation was performed with the following printer(s) to demonstrate

the manufacturing process for the TERA HARZ DENTURE:

| | Brand | Model | Remark |
|---|---|---|---|
| **Design:** | | | |
| **Intraoral scanner** | 3Shape A/S | TRIOS 3 Basic | |
| **Model scanner** | 3Shape A/S | E3 | |
| **Design software** | 3Shape A/S | 3Shape Dental System | |
| **Additive Manufacturing System:** | | | |
| **3D Printer** | SprintRay Inc. | SprintRay Pro 95 | |
| | UNIZ | SLASH 2 | SKU: ZSLP1012001 |
| **Post-Curing:** | | | |
| **Post-cure unit** | CureM | U102H | |

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

The test specimens made of TERA HARZ DENTURE were printed under different output conditions and each specimen was measured using the evaluation criteria of a flexural strength greater than 65 MPa and flexural modulus greater than 2000 MPa. All specimens met the criteria. The optimal output angle is 45 degrees, and the optimal position is the center.

In addition, the repeated usage of the material met the criteria for flexural strength and modulus when reused up to 6 times.

**Performance Testing**

Performance tests in accordance with ISO 20795-1 including visual inspection, capacity, package integrity, surface characteristics, shape capability, porosity, translucency, color, color stability, flexural strength, flexural modulus, water sorption, water solubility, bonding between resin teeth, total fracture work, maximum stress intensity factor were performed. The results of the non-clinical tests demonstrate that the results have met the standard criteria, and the subject device is substantially equivalent to the predicate device.

**Shelf Life Testing**

The Shelf Life Testing Subject device has a shelf life of 1 year.

Shelf-life testing has been conducted with the bench tests from ISO 20975-1.

**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 in contact with the mucosal membrane for > 30 days. The ISO 10993-1 standard was followed and the following biological safety aspects have been addressed:

Cytotoxicity in accordance with ISO 10993-5

Sensitization in accordance with ISO 10993-10

Intracutaneous reactivity in accordance with ISO 10993-10

Irritation in accordance with ISO 10993-10

Acute systemic toxicity in accordance with ISO 10993-11

Sub-chronic toxicity in accordance with ISO 10993-11

Genotoxicity test in accordance with ISO 10993-3

Implantation in accordance with ISO 10993-6

## X. CLINICAL DATA

Clinical performance data was not provided for the TERA HARZ DENTURE.

## XI. CONCLUSIONS

The test results of the non-clinical tests performed on the subject device supported that the device is substantially equivalent to the predicate devices despite the differences. Based on the information provided in this premarket notification, Graphy Inc. concludes that the TERA HARZ DENTURE is substantially equivalent to the predicate device as described herein.