January 14, 2022

Guangzhou Heygears Imc. Inc
Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K213643
Trade/Device Name: UltraPrint-Dental Temp C&B UV
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: November 16, 2021
Received: November 18, 2021

Dear Chris Brown:

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 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

4. Indications for Use Statement

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)*

K213643

Device Name
UltraPrint-Dental Temp C&B UV

Indications for Use *(Describe)*
UltraPrint-Dental Temp C&B UV is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is not more than 28 days in oral environment.

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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K213643
510(k) Summary
GUANGZHOU HEYGEARS IMC.INC
UltraPrint-Dental Temp C&B UV
12/30/2021

ADMINISTRATIVE INFORMATION

Manufacturer Name	GUANGZHOU HEYGEARS IMC.INC Block B2, 501, 601 Enterprise Accelerator, Kaifa District Guangzhou, Guangdong, 510700, China Telephone: +86-17612078809
Official Contact	Lin Liu - Registration Supervisor
Email	hzhang5@heygears.com

DEVICE NAME AND CLASSIFICATION

Proprietary/Device Name:	UltraPrint-Dental Temp C&B UV
Common Name:	Crown and Bridge, Temporary, Resin
Regulation Description:	Temporary Crown And Bridge Resin
Regulation Number:	21 CFR 872.3770
Device Class:	Class II
Product Code:	EBG
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
K200273	FREEPRINT temp	DETAX GmbH & Co.KG

INDICATIONS FOR USE

UltraPrint-Dental Temp C&B UV is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is not more than 28 days in oral environment.

DEVICE DESCRIPTION

The Subject device is a light-cured methacrylate-based resin used in 3D printers for the production of temporary dental restorations. 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, temporary, 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 3D printers and their nesting software, and post-curing devices.

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 tables below compare the Indications for Use and Technological Characteristics of the Subject and Predicate devices.

Indications For Use

Device	Indications for Use Statement
Subject Device UltraPrint-Dental Temp C&B UV GUANGZHOU HEYGEARS IMC.INC	*UltraPrint-Dental Temp C&B UV is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is not more than 28 days in oral environment.*
Predicate Device FREEPRINT temp (K200273) DETAX GmbH & Co.KG	*FREEPRINT temp is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.*

The Subject and Predicate Indications for Use Statement (IFUS) are highly similar, differing only by the device name and two days difference in duration. Slight differences in the wording of the Indications for Use Statements does not change the intended use of the Subject and Predicate and Reference device to fabricate temporary dental restorations.

Technological Characteristics

Parameter	Subject Device UltraPrint-Dental Temp C&B UV GUANGZHOU HEYGEARS IMC.INC	Predicate Device FREEPRINT temp (K200273) DETAX GmbH & Co.KG	Comparison with Predicate Device
Product Code	EBG	EBG	***Same***
Regulation Number	872.3770	872.3770	***Same***
Regulatory Class	Class II	Class II	***Same***
Intended Use	UltraPrint-Dental Temp C&B UV is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is not more than 28 days in oral environment.	FREEPRINT temp is indicated for the fabrication of temporary dental restorations in conjunction with extra-oral curing light equipment. Duration is less than 30 days in oral environment.	***Highly Similar***
Technology	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)	***Highly Similar***
Material Shades	Common VITA-shades	Common VITA-shades	***Same***
Biocompatible	Yes	Yes	***Same***
OTC or Rx	Rx	Rx	***Same***
Sterile	Non-sterile	Non-sterile	***Same***
Chemical Composition	Methacrylate polymer resin with photo initiator, and pigments	(Meth)acrylate-based resin with photo initiator and pigments	***Highly Similar***
Polymerization (Curing) Method	Visible light, 385 nm w/post curing	Visible light, 385 nm w/post curing	***Same***
Equipment	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	***Same***
Performance Testing	ISO 10477:2018	ISO 10477:2018	***Same***
Biocompatibility Testing	ISO 7405:2018 ISO 10993-1:2018 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-6:2016 ISO 10993-10:2013 ISO 10993-11:2017 USP <151>	ISO 7405:2014 ISO 10993-1:2018 ISO 10993-3:2014 ISO 10993-5:2009 ISO 10993-10:2013 ISO 10993-11:2017	***Highly Similar***

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

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

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 device performs similarly to Predicate device.

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 and confirm compatibility with 3D Printers and Post-curing equipment. Assessment of printer compatibility was performed through evaluation of light output, printer resolution, and printer accuracy testing to internal protocols and confirmatory biocompatibility testing.

Physical material property testing was performed on the Subject device to ISO 10477:2018, *Dentistry – Polymer-based crown and veneering materials*. Results demonstrated the Subject device meets the property requirements

of the referenced standard for; Depth of Cure, Flexural Strength, Water Absorption, Water Solubility, Surface Finish, Shade Consistency and Color Stability.

A biological evaluation was performed on the Subject device. Biocompatibility testing was performed on the Subject device according to ISO 10993-1:2018 and ISO 7405:2014. Test included: Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Material-mediated Pyrogenicity, Subacute Toxicity, Genotoxicity and Implantation.

Accelerated and Real-time Shelf life testing was performed to validate device packaging and material stability during storage.

No animal testing data is included in this submission.

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.