November 20, 2025

Guangzhou Heygears Imc. Inc
Mingyang Qu
Co-Founder
Block B2, 501, 601, Enterprise Accelerator, Kaifa District
Guangzhou, Guangdong 510700
China

Re: K253324
Trade/Device Name: UltraPrint-Dental Denture UV
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 29, 2025
Received: September 30, 2025

Dear Mingyang Qu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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
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)*
K253324

Device Name
UltraPrint-Dental Denture UV

Indications for Use *(Describe)*
UltraPrint-Dental Denture UV is indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures.
UltraPrint-Dental Denture UV is intended for continuous use in the oral environment, exclusively for professional dental work.
UltraPrint-Dental Denture UV can be used in combination with a 3D printer using a 385nm light source. A 3D-printer is not part of the device.

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 - K253324
GUANGZHOU HEYGEARS IMC.INC
UltraPrint-Dental Denture UV
September 29th, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name GUANGZHOU HEYGEARS IMC.INC
Block B2, 501, 601, Enterprise Accelerator, Kaifa District, Guangzhou, Guangdong, 510700, China
Phone: +86-020-85446862
Official Contact: Mingyang Qu

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: UltraPrint-Dental Denture UV
Regulation Name: Denture relining, repairing, or rebasing resin
Regulation Number: 21 CFR 872.3760
Regulatory Class: Class II
Product Code: EBI
Review Panel: Dental

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
K200461	FREEPRINT denture	DETAX GmbH & Co.KG.

INDICATION FOR USE

UltraPrint-Dental Denture UV is indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures
UltraPrint-Dental Denture UV is intended for continuous use in the oral environment, exclusively for professional dental work.
UltraPrint-Dental Denture UV can be used in combination with a 3D printer using a 385nm light source. A 3D-printer is not part of the device.

DEVICE DESCRIPTION

The Subject device is a light-cured methacrylate-based resin used in 3D printers for the production of full or partial denture base. The Subject device is used by a dentist or dental technician for the CAD/CAM manufacturing of full or partial denture base
.
The Subject device is used within a validated manufacturing workflow to create the intended dental device. Dental devices fabricated using the Subject device are prescription-only devices.

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 Chemical Composition. 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 Denture UV GUANGZHOU HEYGEARS IMC.INC	UltraPrint-Dental Denture UV is indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures UltraPrint-Dental Denture UV is intended for continuous use in the oral environment, exclusively for professional dental work. UltraPrint-Dental Denture UV can be used in combination with a 3D printer using a 385nm light source. A 3D-printer is not part of the device.
Predicate Device FREEPRINT denture (K200461) DETAX GmbH & Co.KG	FREEPRINT denture is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full andpartial removable dentures. FREEPRINT denture is intended for continuous use in the oral environment, exclusively for professional dental work. FREEPRINT denture can be used in combination with a stereolithographic 3D printer using a 385nm light source. A 3Dprinter is not part of the device.

The Subject and Predicate Indications for Use Statement (IFUS) are highly similar, differing only by the device name and the compatible 3D printer's name. Slight differences in the wording of the Indications for Use Statements does not change the intended use of the Subject and Predicate device to fabricate all types of denture bases, for instance full and partial removable dentures.

Technological Characteristics

Parameter	**Subject Device** UltraPrint-Dental Denture UV	**Predicate Device** (Resin for Temporary Crown & Bridge, Dentis Co., Ltd. ,K180657)	**Comparison with Predicate Device**
Product Code	EBI	EBI	Same
Device	Resin, Denture, Relining, Repairing, Rebasing	Resin, Denture, Relining, Repairing, Rebasing	Same
Regulation Number	21 CFR 872.3760	21 CFR 872.3760	Same
Regulatory Class	Class II	Class II	Same
Intended use	UltraPrint-Dental Denture UV is indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures	FREEPRINT denture is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full andpartial removable dentures.	Highly Similar

	UltraPrint-Dental Denture UV is intended for continuous use in the oral environment, exclusively for professional dental work. UltraPrint-Dental Denture UV can be used in combination with a 3D printer using a 385nm light source. A 3D-printer is not part of the device.	FREEPRINT denture is intended for continuous use in the oral environment, exclusively for professional dental work. FREEPRINT denture can be used in combination with a stereolithographic 3D printer using a 385nm light source. A 3Dprinter is not part of the device.	
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	Same
Biocompatible	Yes	Yes	Same
OTC or Rx	Rx	Rx	Same
Sterile	Non-sterile	Non-sterile	Same
Chemical Composition	Dimethacrylate based resin with photo intiator, and pigments	Dimethacrylate based resin with photo intiator, and pigments	Highly Similar
Polymerizaion (Curing) Method	UV Light, 385nm post curing	UV Light, 385nm post curing	Same
Equipment	Validated 3D-Printer and post curing unit	Validated 3D-Printer and post curing unit	Same
Performance Testing	ISO 20795-1:2013	ISO 20795-1:2013	Same
Biocompatibility Testing	ISO 7405 ISO 10993-1 ISO 10993-3 ISO 10993-6 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-17 ISO 10993-18 ISO 10993-23 USP<151>	ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO 10993-17, ISO 7405	Highly Similar

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

Indications For Use - The Subject and Predicate Indications for Use Statement (IFUS) are highly similar, differing only by the device name and the compatible 3D printer’s name. 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 all types of denture bases, for instance full and partial removable dentures.

Material/Chemical Composition - The Subject and Predicate devices are same in they are both UV-light cured liquid dimethacrylate based resin with photo intiator, and pigments. Slight differences in chemical composition do not change the intended use of the Subject and Predicate devices to be used in the fabrication of full or partial denture base. The Subject device has demonstrated suitability for intended use through material non-clinical performance testing.

Non-clinical performance testing of the Subject device met the acceptance criteria for each test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use, 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.

Physical property testing was performed on the Subject device to ISO 20795-1:2013 *Dentistry — Base polymers Part 1: Denture base polymers.* Results demonstrated the Subject device meets the property requirements of the referenced standard.

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 7405:2025.

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. 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.