August 13, 2026

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

Re: K261626
Trade/Device Name: UltraPrint Flexible Denture UV
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: May 15, 2026
Received: May 15, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261626

Device Name
UltraPrint Flexible Denture UV

Indications for Use *(Describe)*
UltraPrint Flexible Denture UV is indicated for the fabrication of partial removable dentures and intended for continuous use not to exceed 30 days and until the permanent denture is fabricated and placed. It is intended exclusively for professional dental work.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K261626 - 510(k) Summary
GUANGZHOU HEYGEARS IMC.INC
UltraPrint Flexible Denture UV
8/10/2026

ADMINISTRATIVE INFORMATION

Manufacturer Name	GUANGZHOU HEYGEARS IMC.INC Block B2, 501, 601 Enterprise Accelerator, Kaifa District Guangzhou, Guangdong, 510700, China Telephone: +86 020-28186347
Official Contact	Mingyang Qu, Co-Founder
Email	hzhang5@heygears.com

DEVICE NAME AND CLASSIFICATION

Proprietary/Device Name:	UltraPrint Flexible Denture UV
Common Name:	Resin, Denture, Relining, Repairing, Rebasing
Classification Name:	Denture relining, repairing, or rebasing resin
Classification Regulation:	21 CFR 872.3760
Device Class:	Class II
Product Code:	EBI
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
K250617	Apex Flex	SprintRay Inc.

INDICATIONS FOR USE

UltraPrint Flexible Denture UV is indicated for the fabrication of partial removable dentures and intended for continuous use not to exceed 30 days and until the permanent denture is fabricated and placed. It is intended exclusively for professional dental work.

DEVICE DESCRIPTION

The Subject device is a light-cured methacrylate-based resin used by a dental professional (dentist or dental technician) for the CAD/CAM manufacturing of patient-specific temporary partial dentures. There are four models or “shades” of the Subject device which are referred to as Pink, Dark Pink, Opaque Pink and Transparent. The “Pink” models include additional pigments to provide a degree of pink color to the final printed denture. 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.

Commonly used dental CAD software is used by dental professionals to virtually design a flexible denture framework and generate an industry-standard "STL" 3D dataset which reflects the intended shape and contour. The Subject device resin is used within a validated additive manufacturing workflow to create the intended framework.

The Subject device is provided in HPDE bottles. Dental devices fabricated using the Subject device are one-time use, prescription-only devices. The Subject device is intended for continuous use not to exceed 30 days and until the permanent denture is fabricated and placed.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

Biocompatibility testing according to:

- ISO 10993-1 Evaluation and testing within a risk management process
- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitization
- ISO 10993-11 Material Mediated Pyrogenicity/Systemic Toxicity
- ISO 10993-23 Irritation/Intracutaneous Reactivity

Bench Performance testing:

- Material Property Testing of each shade to ISO 20795-1
- Comparative Testing with the Predicate device to specific ISO 20795-1 endpoints
- Manufacturing Validation/Placement Orientation/Printer Compatibility
- Recycle/Re-use
- Service Life
- Shelf Life

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. The non-clinical performance testing performed demonstrates that the Subject device is suitable for intended use.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent in Indications for Use, Technological Characteristics, and design principles to Predicate device listed above. The Summary tables at the end of this section compare the Subject and Predicate devices.

Indications for Use

Predicate Device K250617, Apex Flex

The Subject device Indications for Use Statement (IFUS) is similar to that of the K250617 Predicate device. The device name differs, but that does not impact the indications or intended use of the devices. They both indicate the devices are intended for use in fabricating partial dentures. The wording is slightly different but expresses the same intent. The Subject device IFUS includes additional clarifying language regarding the duration of use, but that does not change the intended use of partial denture fabrication.

Technological Characteristics

Predicate Device K250617, Apex Flex

The Subject and Predicate devices are highly similar or the same in all Technological Characteristics. The intended use of the Subject and Predicate devices are the same. The Predicate device is leveraged for comparative ISO 20795-1 material performance testing endpoints to demonstrate substantial equivalence. The Predicate device is leveraged for the use of 3D printing technology in conjunction with denture base resin. The Subject device offers additional denture base shades relative to the Predicate device, but those differences are mitigated through performance testing on the additional Subject device shades. The Subject device was tested to biocompatibility endpoints related to the intended device use and duration some of which may differ than the Predicate device tested endpoints, but that does not change the intended use of the device or impact substantial equivalence.

Conclusion

Overall, the Indications for Use statements of the Subject device and the K250617 Predicate are highly similar, differing in the device name and descriptive wording. The intended use is the same.

Overall, the Technological Characteristics of the Subject device are highly similar or the same as the Predicate device, including material performance to ISO 20795-1 testing endpoints.

Overall, the Subject device is substantially equivalent to the Predicate device.

Comparison - Indications for Use Statement

Subject Device UltraPrint Flexible Denture UV HeyGears	**Predicate Device** Apex Flex SprintRay Inc. K250617
UltraPrint Flexible Denture UV is indicated for the fabrication of partial removable dentures and intended for continuous use not to exceed 30 days and until the permanent denture is fabricated and placed. It is intended exclusively for professional dental work.	*SprintRay Apex Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work.*

Comparison of Technological Characteristics

Comparison	**Subject Device** UltraPrint Flexible Denture UV HeyGears	**Predicate Device** Apex Flex SprintRay Inc. K250617
Product Code	EBI	EBI
Regulation	21 CFR 872.3760	21 CFR 872.3760
Intended Use	Used in the fabrication of flexible partial removable dentures.	Used in the fabrication of flexible partial removable dentures.
Reason for Predicate/Reference	Not Applicable	Intended use, manufacturing process, material properties
Material Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM
Material	Methacrylate resin, photo initiator	Methacrylate resin, photo initiator
Shades	Pink, Dark Pink, Opaque Pink and Transparent	Light Pink, Standard Pink
Polymerization (Curing) Method	UV light, 385 nm w/post curing	UV light, 385 nm w/post curing
Prescription device	Yes	Yes
Manufacturing Equip	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices
Performance Testing	ISO 20795-1	ISO 20795-1
Biocompatibility Testing	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23	ISO 7405 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-23
Biocompatibility	Yes	Yes
Sterile	No	No