March 2, 2026

Guangzhou Heygears IMC., Inc.
Meifang Liu
Regulatory Affairs
Block B2, 501,601, Enterprise Accelerator, Kaifa District
Guangzhou, Guangdong 510700
CHINA

Re: K253798
Trade/Device Name: UltraPrint-Dental Hard Splint UV
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: January 30, 2025
Received: January 30, 2025

Dear Meifang Liu:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253798

Device Name
UltraPrint-Dental Hard Splint UV

Indications for Use *(Describe)*
The UltraPrint-Dental Hard Splint UV device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers.

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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510K summary

I. SUBMITTER

GUANGZHOU HEYGEARS IMC.INC
Block B2, 501, 601, Enterprise Accelerator, Kaifa District, Guangzhou, Guangdong, 510700, China
Phone: +86-020-28186347
Contact Person: Meifang Liu
Date Prepared: February 28, 2026

II. DEVICE

Name of Device: UltraPrint-Dental Hard Splint UV
Trade name of Device: UltraPrint-Dental Hard Splint UV; UltraPrint Hard Splint UV; Hard Splint UV;
Common or Usual Name: Dental Resin for 3D printing，Mouthguard
Classification Name: Mouthguard, Unclassified; Positioner, 872.5525
Regulatory Class: Unclassified
Product Code: MQC

III. PREDICATE DEVICE

KeyPrint@ KeySplint Hard K203000

No reference devices were used in this submission

IV. Device Description

UltraPrint-Dental Hard Splint UV is a light-curing resin based on acrylate, biocompatible, for the generative fabrication of splint for DLP printers with UV-LED 385 nm. The material is a polymer undergoes polymerization and cross-linking reaction under the action of photo-initiation when exposed to UV light, which makes the resin material polymerize to a solid state at high speed.

Key property as shown below.

Ultimate flexural strength	≥50MPa
Flexural elastic modulus	≥1500MPa

V. Indications for Use

The UltraPrint-Dental Hard Splint UV device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers.

VI. Comparison of technological characteristics with predicate device

UltraPrint-Dental Hard Splint UV is similar to predicate device in raw material and processing. Both resins are manufactured using very similar components and are

processed into the final device using 3D printing and light curable polymerization. They share same indication for use, same material composition(UV curable resin,photo Initiator and pigments),same DLP printing technology, same compliance with ISO 20795-2 regarding chemical,physical and mechanical performance, and both compliant with ISO10993-1 in terms of biological safety. A difference between UltraPrint-Dental Hard Splint UV and predicate device KeyPrint® KeySplint Hard lies in the specific formula/chemical compositions. The formulation of UltraPrint-Dental Hard Splint UV was developed based on FDA-marketed dental resin/monomer and the ratio of those composition is tailored to achieve both ISO20795 compliance and clinical needs.The biological concern for potential difference in formula/chemical composition is addressed and further biological evaluation(chemical characterization, toxicological evaluation, and biological test). The result shows that UltraPrint-Dental Hard Splint UV is biocompatible for its intended use.

VII. Non-Clinical DATA

Physical /Mechanical performance

The physical properties of the subject device were determined and tested according to ISO 20795-2:2013, ASTM standard and internal inspection standard, and the test results demonstrated the qualification and substantial equivalence when compared to the predicate device.

Physical / Mechanical Property	Standard	Acceptance Criteria	If the test met the acceptance criteria?
Ultimate Flexural Strength	ISO 20795-2	>50MPa	Yes
Flexural Modulus		>1500MPa	Yes
Water Sorption		<32ug/mm3	Yes
Solubility		<5ug/mm3	Yes
K factor		>1.1 MPa $m^{1/2}$	Yes
Fracture work		>250 J/m^2	Yes
Free Monomer Extraction		<2.2%	Yes
Flexural Strength	ASTM D790	>50MPa	Yes
Flexural Modulus		>1500MPa	Yes
Shore D Hardness	ASTM D2240	>80D	Yes
IZOD Impact(Notched)	ASTM D256	N/A	N/A
Color	N/A	N/A	N/A
Density	N/A	N/A	N/A

Additive Manufacturing Process validation

According to FDA's guidance Technical Considerations for Additive Manufactured Medical Devices(issued on December 5, 2017), studies were performed to demonstrate repeatability,physical properties, build orientation, reuse&recycling, and validation of compatible system.Results shows that under various conditions as challenged, the finial device as manufactured meet the performance requirements as specified in ISO 20795-2:2013.

Biocompatibility

The compositions of the subject device do not contain any non-conventional chemicals compared to the legally marketed predicate and reference devices.
Biocompatibility tests were performed fully following the ISO 7405 and ISO 10993 standards, including Cytotoxicity, Irritation, Sensitization, Chemical Characterization and Toxicological assessment and results are sufficient to prove the subject device is substantially equivalent to the predicate device.
The device met the acceptance criteria of the ISO 7405 and ISO 10993 standards.
No clinical testing were performed for UltraPrint-Dental Hard Splint UV.

Reprocessing

The cleaning method is validated according to AAMI ST98:2022 (Cleaning validation of health care products-Requirements for development and validation of a cleaning process for medical devices) .

Shelf life

The shelf life of UltraPrint-Dental Hard Splint UV is 2 years.
Accelerated /Real aging
Following ASTM F1980 - 21 (Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices) and ISO 20795-2:2013(Dentistry — Base polymers Part 2: Orthodontic base polymers), accelerated aging test were conducted, which involves inspection in the homogeneity, surface characteristics, polishability, colour, freedom from porosity, ultimate flexural strength, flexural modulus,maximum stress intensity factor,total fracture work,residual methyl methacrylate monomer, water absorption, water solubility and packaging integrity. The result shows that after 2 years and 3 months accelerated aging, the device meet ISO20795-2:2013 and the packaging integrity remain its conformance with packaging specification. Real-time aging is in process, so far no nonconformity was detected.
Unsealing lifetime verification
Heygears has conducted 45-day unseal aging testing and confirmed its conformity with ISO 20795-2 requirement.It is verified that the material stability of UltraPrint-Dental Hard Splint UV in unsealed bottles can be maintained for at least 30 days.

VIII. CONCLUSIONS

The intended use,technical characteristic, are substantially equivalent to the predicate device. The stability of resin/final finished device, and the additive manufacturing method/cleaning method as recommended in IFU are verified according to FDA recognized standards/guidance.

While the formula of subjective resin is different from the Predicate, both are light curable acrylate resins used in additive manufacturing and are from the same material category, commonly used for fabricating customized dental splints. The additive manufacturing processes both use the light curable resins, validated printers and curing

units. Biocompatibility evaluation according to FDA recognized standard/guidance demonstrate positive result. The differences, in comparison to the Predicate device, raise no new questions of safety and effectiveness. Based on the physical performance and biocompatibility test results of the UltraPrint-Dental Hard Splint UV material, it has been confirmed that this device meets all the necessary standards and prove the subjective device is substantially equivalent to the predicate device.