October 30, 2026

Hangzhou SHINING3D Dental Technology Co., Ltd.
% Dave Yungvirt
Third Party Review Group, LLC
1887 Whitney Mesa Dr.
Suite 1960
Henderson, Nevada 89014

Re: K263860
Trade/Device Name: Shining3D Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 29, 2026
Received: October 29, 2026

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 (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 13484 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
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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)*
K263860

Device Name
Shining3D Clear Aligner System

Indications for Use *(Describe)*
Shining3D Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e.all second molars). Shining3D Clear Aligner System repositions teeth by way of continuous gentle force.

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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K263860

510(k) Summary

I Submitter

Submitter Name:	Hangzhou SHINING3D Dental Technology Co., Ltd.
Establishment Registration Number：	3026312357
Submitter Address:	9-5-2, Tri-River Valley, Wenyan Street, Xiaoshan, Hangzhou, Zhejiang, 311258, China
Contact Person:	Chen Yuting Title: Regulatory Affairs Specialist Phone: +86 15600612898 Email: chenyuting@shining3d.com
Date Prepared:	Oct. 27 th, 2026

II Device

Device Name:	Shining3D Clear Aligner System
Model:	ARV1
Regulation Name:	Orthodontic Plastic Bracket
Regulation Number:	21 CFR 872.5470
Regulatory Class:	Class II
Product Code:	NXC
Review Panel:	Dental

III Predicate Device

Trade/Device Name:	LuxCreo Clear Aligner System
Regulation Name:	Orthodontic Plastic Bracket

Regulation Number:	21 CFR 872.5470
Regulatory Class:	Class II
Product Code:	NXC
Submitter Name:	LuxCreo Inc.
510(k) Number:	K212680

IV Device description

The product should be used in combination with SHINING3D printer. The product is a liquid photo-curable material, which is produced by free radical polymerization of (meth) acrylate oligomers and monomers triggered by photo-initiator contained in the resin. The resin is printed in multiple layers automatically, with each layer being subjected to light curing before the addition of the next layer, and then undergoes post-curing in a curing device. The product is intended exclusively for professional dental work.

V Intended Use /Indications for use

Shining3D Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e.all second molars). Shining3D Clear Aligner System repositions teeth by way of continuous gentle force.

VI Available model and Specification

Model: ARV1

Specification: 1 kg/bottle

VII Summary of the Technological Characteristics

Both the subject device and predicate device use light-cured additive manufacturing to fabricate patient-specific, removable orthodontic aligners from methacrylate-based resin systems.

Subject device and predicate device are substantially equivalent in the following points:

- Intended use
- Prescription status (Rx only)
- Duration of use
- Application
- Underlying technology
- Design
- Non-sterile status
- Performance compliance
- Biocompatibility evaluation framework

The following difference may be noted between subject device and predicate device:

- Raw material constituents
- Exact manufacturing equipment parameters
- Shelf-life duration
- Physical and mechanical properties

Analysis 1: Materials

Both the subject device and the predicate device are manufactured from biocompatible, non-sterile methacrylate-based resin, which supports a finding of substantial equivalence. This class of material is widely used for resins for additively manufactured orthodontic appliances. The subject device has completed biological evaluation and meets applicable biocompatibility requirements.

The subject device and the predicate device share the same primary base resin component. Differences exist only in additives and the loading ratios of each constituent. These variations do not introduce new safety or effectiveness risks, as both devices meet the specified performance and biocompatibility standards.

Analysis 2: Equipment

Both the subject device and the predicate device are produced using validated 3D printers and post-curing equipment for orthodontic intended use. The subject device is compatible with its corresponding equipment. Printing and post-curing parameters have been fully verified. Both the subject device and the predicate device meet applicable performance and safety requirements. Differences in equipment do not affect the finding of substantial equivalence.

Analysis 3: Shelf-Life

The subject device has a 2-year shelf-life, compared with 6 months for the predicate device. The subject device has completed shelf-life validation, demonstrating that it meets usage requirements throughout its 2-year shelf-life. Differences in shelf-life do not affect the finding of substantial equivalence.

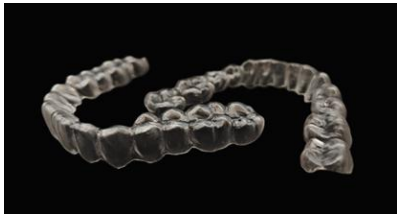
Analysis 4: Physical and Mechanical Properties

The physical and mechanical properties of both the subject device and the predicate device comply with ISO 20795-2:2013. The key indicators, including ultimate flexural strength, flexural modulus, water absorption, water solubility and Shore D hardness, for the subject device are no worse than those of the predicate device. Differences in physical and mechanical properties do not affect the finding of substantial equivalence.

In addition, the subject device was tested for maximum stress intensity factor, total fracture work, appearance, surface characteristics, shape capability, colour, freedom from porosity, and viscosity. All test results meet the acceptable criteria.

In summary, the subject device is substantially equivalent to the predicate device.

The following table shows comparison and discussion between the subject device and the predicate device.

Items	Subject device	Predicate device	Remark
Product Name	Shining3D Clear Aligner System	LuxCreo Clear Aligner System	--
Regulation Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	Same
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Regulatory Class	Class II	Class II	Same
Indication for Use /Intended Use	Shining3D Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e.all second molars). Shining3D Clear Aligner System repositions teeth by way of continuous gentle force.	The LuxCreo Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.	Same
OTC or Rx	Rx	Rx	Same
Duration of Use	20~22 hours/day	20~22 hours/day	Same
Application	Removable	Removable	Same
Technology	Light-cured 3D printing	Light-cured 3D printing	Same
Materials	(Meth) acrylate oligomers and monomers, photo-initiator, and additives.	Light-cured polyurethane resin.	Similar (Analysis 1)
Design			Same

Items	Subject device	Predicate device	Remark
Equipment	Validated 3D-Printer and post curing devices.	DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing.	Similar design (Analysis 2)
Sterile	Non-sterile	Non-sterile	Same
Shelf-Life	2 years	6 months	Different (Analysis 3)
Performance Testing	ISO 20795-2:2013	ISO 20795-2:2013	Same
Physical and mechanical properties	Ultimate flexural strength: 38.09±0.39 MPa Flexural modulus: 1037.61±56 MPa Water absorption: 4.02±0.6128 μg/mm^3 Water solubility: 0.436±0.0672 μg/mm^3 Shore D Hardness: 68±1.0 H_D Maximum stress intensity factor: 2.16±0.06 MPa·m$^{1/2}$ Total fracture work: 1844.15±48.60 J/m^2 Appearance: Acceptable Surface characteristics: Acceptable Shape capability: Acceptable Colour: Acceptable Freedom from porosity: Acceptable Viscosity: Acceptable	Ultimate flexural strength: 23.6±1.9 Mpa Flexural modulus: 804±64 MPa Water absorption: 19.952±6.6719 μg/mm^3 Water solubility: 3.668±1.0748 μg/mm^3 Shore D Hardness: 21.63±0.38 H_D	Different (Analysis 4)
Biocompatibility	ISO 10993-3 Genotoxicity test -In vitro Mouse Lymphoma Assay ISO 10993-3 Genotoxicity test -In vitro Bacterial Reverse Mutation Assay ISO 10993-5 In vitro Cytotoxicity ISO 10993-6 Subcutaneous Implantation Test	ISO 10993-3 Genotoxicity test ISO 10993-5 In vitro Cytotoxicity ISO 10993-6 Subcutaneous Implantation Test ISO 10993-10 Oral Mucosa Irritation Pyrogen ISO 10993-10 Skin Sensitization in Guinea Pigs	Same

Items	Subject device	Predicate device	Remark
	ISO 10993-10 Guinea Pig Maximization Sensitization Test ISO 10993-11 Acute Systemic Toxicity Test ISO 10993-11 Subchronic Systemic Toxicity Test ISO 10993-11Material Mediated Pyrogen Test ISO 10993-23 Oral Mucosa Irritation Test	(Maximization Test) ISO 10993-11 Acute Systemic Toxicity ISO 10993-11 Subchronic systemic toxicity	

VIII Summary of Testing (Performance Data)

Biocompatibility testing:

Based on ISO 10993-1 and ISO 7405, the subject device is categorized as a surface device with long-term mucosal membrane contact (>30 days). Biocompatibility tests were performed on worst-case post-cured finished device samples. The evaluation included:

- Cytotoxicity Test
- Sensitization Test
- Irritation or intracutaneous reactivity
- Acute Systemic Toxicity Test
- Subchronic toxicity
- Implantation effects Test
- Genotoxicity Test (In vitro Mouse Lymphoma Assay, In vitro Bacterial Reverse Mutation Assay)
- Pyrogen Test

All biocompatibility endpoints met the pre-defined acceptance criteria, supporting the safety of the device for its intended use.

Chemical characterization and toxicological risk assessment：

Chemical characterization and toxicological risk assessment (TRA) were performed on worst-case finished device samples of the Shining3D Clear Aligner System. Exhaustive extraction and additional simulated-use leachables testing in artificial saliva were performed. Conservative exposure assumptions were applied to calculate Margin of Safety (MOS). Under clinically relevant conditions, all detected compounds yielded MOS >1. The TRA demonstrates that the toxicological risk associated with extractables and leachables from the device is acceptable.

Performance testing:

The physical and mechanical properties of the subject device were evaluated in accordance with the FDA-recognized version of ISO 20795-2, Dentistry - Base polymers - Part 2: Orthodontic base polymers. The test results demonstrate that the subject device meets the property requirements of the referenced standard.

Manufacturing Validation

Validation of the manufacturing process and compatible equipment was performed demonstrating consistency of the process output with that of the process input.

IX Clinical Data

No clinical studies were included in this submission.

X Conclusion

The subject device is as safe and effective as its predicate device. The subject device shares the same intended use, technology, design, and similar material and performance characteristics.

The minor differences between the subject device and the predicate device do not raise additional safety or effectiveness concerns, supported by the relevant tests and evaluations provided in this submission. Performance data confirm that the subject device demonstrates equivalent safety and effectiveness to the predicate device.

Therefore, the Shining3D Clear Aligner System is substantially equivalent to the LuxCreo Clear Aligner System.