April 17, 2026

Hangzhou SHINING3D Dental Technology Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120a
Madison, New Jersey 07940

Re: K261261
Trade/Device Name: Dura-Arch
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary crown and bridge resin
Regulatory Class: Class II
Product Code: EBG PZY
Dated: April 16, 2026
Received: April 16, 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
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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)*
K261261

Device Name
Dura-Arch

Indications for Use *(Describe)*
The product is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and preformed denture teeth to be used in a denture.

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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K261261

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 Yuqi Title: Regulatory Affairs Specialist Phone: +86 18868106483 Email: chenyuqi@shining3d.com
Date Prepared:	April 1, 2026

II Device

Device Name:	Dura-Arch
Model:	CX200-A1 / CX200-A2 / CX200-B1 / CX200-BL
Regulation Name:	Temporary Crown and Bridge Resin
Regulation Number:	21 CFR 872.3770
Regulatory Class:	Class II
Product Code:	EBG, PZY
Review Panel:	Dental

III Predicate Device

Trade/Device Name:	GR-17 Resin System
Regulation Name:	Temporary Crown and Bridge Resin

Regulation Number:	21 CFR 872.3770
Regulatory Class:	Class II
Product Code:	EBG, PZY
Submitter Name:	Pro3dure Medical GmbH
510(k) Number:	K201827

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 oligomers triggered by photoinitiator 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

The product is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and preformed denture teeth to be used in a denture.

VI Available model

Model	Color
CX200-A1	A1
CX200-A2	A2
CX200-B1	B1
CX200-BL	0M2

VII Comparison to predicate devices

The subject device is as safe and effective as its predicate device. It shares the same or similar intended use, chemical description, manufacturing and curing method etc., with performance characteristics that are either identical or substantially equivalent to those of predicate device.

Additionally, the subject device is indicated for the fabrication of preformed denture teeth to be used in a denture, which fall under the product code "PZY" (Additively Manufactured, Preformed, Resin Denture Tooth) and are 510k exempt, therefore out of the scope of this submission.

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

Item	Subject Device	Predicate Device (K201827)	Remark
Product Name	Dura-Arch	GR-17 Resin System	--
Regulation Name	Temporary Crown and Bridge Resin	Temporary Crown and Bridge Resin	Same
Product Code	EBG, PZY	EBG, PZY	Same
Regulation Number	21 CFR 872.3770	21 CFR 872.3770	Same
Regulatory Class	Class II	Class II	Same
Indication for Use /Intended Use	The product is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and preformed denture teeth to be used in a denture.	The GR-17 Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The GR-17 temporary is indicated for the fabrication, by additive	Similar

		manufacturing, of temporary anterior dental restorations. The GR-17.1 temporary is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and for the fabrication, by additive manufacturing, of preformed denture teeth to be used in a denture.	
Chemical Description	Dura-Arch consists of (meth)acrylate oligomers and monomers, photo-initiator, pigments and absorbers.	Methacrylate- based resin	Similar
Acrylic Resin	Extra-oral light cure resin	Extra-oral light cure resin	Same
Manufacturing	Additive	Additive	Same
Curing Method	UV Light	UV Light	Same
Product State	Liquid	Liquid	Same
Equipment	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Same
Shelf-Life	2 years	2 years	Same
Sterile	Non-sterile	Non-sterile	Same
Performance Testing	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	Same
Flexural Strength	≥ 50 MPa	≥ 100 MPa	Similar
Water Sorption	≤ 40 µg/mm^3	≤ 40 µg/mm^3	Same
Solubility	≤ 7.5 µg/mm^3	≤ 7.5 µg/mm^3	Same
Biocompatibility Testing	Comply with ISO 10993-1:2018, and ISO 7405:2018	Comply with ISO 10993-1:2018, and ISO 7405:2018	Same

VIII Summary of Testing (Performance Data)：

Non-Clinical Performance Test Conclusion

Biocompatibility testing

Based on ISO 10993-1 and ISO 7405, the subject device is categorized as a surface device in contact with mucosal membrane with Long-term contact (>30d). The subject device was evaluated for:

- Cytotoxicity Test
- Sensitization Test
- Oral Mucosa Irritation Test
- Intracutaneous Reactivity Test
- Acute Systemic Toxicity Test
- Subchronic Systemic Toxicity Test
- Implantation Test
- Pyrogen Test
- Genotoxicity Test

Performance Bench Testing:

Physical and mechanical properties of the subject device were evaluated according to:

- ISO 4049:2019 Dentistry - Polymer-based restorative materials

- ISO 10477:2020 Dentistry - Polymer-based crown and veneering materials.

- ISO 22112:2017 Dentistry - Artificial teeth for dental prostheses

The test results demonstrated the Subject device meets the property requirements of the referenced standards.

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

Shelf-Life Testing:

The shelf-life of the Dura-Arch is 2 years. Testing was performed in accordance with ASTM F1980-21.

Clinical Test Conclusion:

No clinical study is included in this submission.

IX Conclusion

The subject device is as safe and effective as its predicate device. It shares the same or similar intended use, chemical description, manufacturing and curing method etc., with performance characteristics that are either identical or substantially equivalent to those of predicate device.

The minor differences among the subject device and predicate device have not raised extra safety and performance concerns, based on 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.

Thus, the Dura-Arch is substantially equivalent.