April 27, 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: K261356
Trade/Device Name: Dura-Crown
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBG, PZY
Dated: April 24, 2026
Received: April 24, 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)*
K261356

Device Name
Dura-Crown

Indications for Use *(Describe)*
Dura-Crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. Dura-Crown is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. Dura-Crown can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

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.

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K261356

510(k) Summary

I Submitter

Submitter Name:	Hangzhou SHINING3D Dental Technology Co., Ltd.
Submitter Address:	9-5-2, Tri-River Valley, Wenyan Street, Xiaoshan, Hangzhou, Zhejiang, 311258, China
Registration Number	3026312357
Contact person:	Yang Jiachen Regulatory Affairs Supervisor +86-19829816259 yangjiachen@shining3d.com
Date Prepared:	24 April, 2026

II Device

Trade Name of Device:	Dura-Crown
Classification Name(s)	Tooth shade resin material
Model:	CB21-A1/CB21-A2/CB21-A3/CB21-B1
Regulation number	21 CFR 872.3690
Regulatory class:	Class II
Product Code:	EBF, EBG, PZY
Review Panel:	Dental

III Predicate Device

Trade name:	Dura-Crown
Classification Name(s):	Tooth shade resin material
Regulation number:	21 CFR 872.3690
Regulatory class:	Class II
Product code:	EBF, EBG, PZY
Submitter Name:	Hangzhou SHINING3D Dental Technology Co., Ltd.
510(k) number:	K253053

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 a photoinitiator contained in the resin. Automated printing of the resin in multiple layers, each light-cured before adding next layer, are post cured in the cure device.The product is intended exclusively for professional dental work.

V Indications for use

Dura-Crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. Dura-Crown is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. Dura-Crown can also be used for the fabrication of artificial teeth and temporary crowns & bridges.

VI Available model

Model	Color	Specification
CB21-A1	A1	0.5kg/bottle；Nano
CB21-A2	A2	
CB21-A3	A3	
CB21-B1	B1	

VII Comparison to predicate devices

Item	Subject device	Predicate device	Comparison with Changes
Product Name	Dura-Crown	Dura-Crown	**Same, No changes**
510(k) Number		K253053	**N/A**
Classification name	Tooth shade resin material	Tooth shade resin material	**Same, No changes**
Product Code	EBF, EBG, PZY	EBF, EBG, PZY	**Same, No changes**
Device Classification	Class II	Class II	**Same, No changes**
Specification	0.5kg/bottle	0.5kg/bottle, Nano	**New specification added**
Submitter Name	Hangzhou SHINING3D Dental Technology Co., Ltd.	Hangzhou SHINING3D Dental Technology Co., Ltd.	**Same, No changes**

Item	Subject device	Predicate device	Comparison with Changes
Indication for Use/Intended Use	Dura-Crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. Dura-Crown is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. Dura-Crown can also be used for the fabrication of artificial teeth and temporary crowns & bridges.	Dura-Crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. Dura-Crown is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. Dura-Crown can also be used for the fabrication of artificial teeth and temporary crowns & bridges.	**Same, No changes**
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	**Same, No changes**

Item	Subject device	Predicate device	Comparison with Changes
Chemical Description	(Meth)acrylate oligomers and monomers, photo-initiator, fillers, additives and pigments.	(Meth)acrylate oligomers and monomers, photo-initiator, fillers, additives and pigments.	**Same, No changes**
Equipment	3D Printer:AccuFab-D1s/C1s Post-curingUnit:FabCure2	3D Printer:AccuFab-D1s/C1s Post-curingUnit:FabCure2 3D printer with post-curing function: Ceramix-Nano	**New supporting equipment added**
Packaging	The specification of 0.5kg/bottle is packaged in a separate inner packing box containing a black plastic bottle.Each outer packaging contains six inner boxes.	The specification of 0.5kg/bottle is packaged in a separate inner packing box containing a black plastic bottle.Each outer packaging contains six inner boxes. The specification of Nano has content of 5g, 8g, 26g, 3 Unit in a pack, it is packaged in a plastic conta containing 3	**New packaging added**

Item	Subject device	Predicate device	Comparison with Changes
		Nano cartridges. Each outer packaging contains a plastic conta. And a content of of 65g, 1 Unit in a pack, it is packaged in a plastic conta containing 1 Nano cartridges. Each outer packaging contains a plastic conta.Also, there is a outer packaging box(transportation packaging) for Nano conta.	
Contraindication, warning	Do not use the product in case of a known allergy to one or more ingredients(such as acrylate).	Do not use the product in case of a known allergy to one or more ingredients(such as acrylate).	**Same, No changes**
Material Type	Methacrylate-based polymer resin	Methacrylate-based polymer resin	**Same, No changes**
Material Shades	Common VITA-shades	Common VITA-shades	**Same, No changes**

Item	Subject device	Predicate device	Comparison with Changes
Biocompatible	Yes	Yes	**Same, No changes**
Sterile	Non-sterile	Non-sterile	**Same, No changes**
Curing Method	UV Light	UV Light	**Same, No changes**
Shelf-Life	2 years	2 years	**Same, No changes**
Performance Testing	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	**Same, No changes**
Flexural strength	≥120MPa	≥120MPa	**Same, No changes**
Biocompatibility Testing	ISO 10993-1:2018 ISO 7405:2018	ISO 10993-1:2018 ISO 7405:2018	**Same, No changes**

VIII Changes description

In response to commercial demand, the changes were implemented under design control procedures: the introduction of a new "Nano" product specification, which involves a new packaging configuration, and the qualification of a new supporting 3D printing device.

We conducted a design review and risk analysis (per ISO 14971) to assess the impact of these changes. The risk assessment confirmed that the change in bottle size and associated packaging does not alter the material formulation, curing properties, or chemical composition of the resin itself, thus presenting no new hazards related to material safety or device performance. Consequently, the plan focused on performance testing using the new printer and the stability of new packaging which should demonstrate that the changes in container size and printing platform do not adversely affect the safety or effectiveness of the final medical device.

IX Conclusion

The specification expansion for “Nano”, packaging optimization, and supporting equipment extension changes involved in this application have not altered the device’s core formulation, manufacturing process, intended use, indications for use, or the foundation of safety and effectiveness.

All changes have undergone adequate verification and validation, demonstrating substantial equivalence to the marketed predicate device.