September 23, 2025

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

Re: K253053
Trade/Device Name: Dura-Crown (CB21-A1/CB21-A2/CB21-A3/CB21-B1)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF, EBG, PZY
Dated: September 20, 2025
Received: September 22, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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)*
K253053

Device Name
Dura-Crown (CB21-A1/CB21-A2/CB21-A3/CB21-B1)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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, China
Registration Number	3026312357
Contact person:	Yang Jiachen Regulatory Affairs Supervisor +86-19829816259 yangjiachen@shining3d.com
Date Prepared:	September 20, 2025

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:	VarseoSmile TriniQ
Classification Name(s):	Tooth shade resin material
Regulation number:	21 CFR 872.3690
Regulatory class:	Class II
Product code:	EBF, EBG, PZY
Submitter Name:	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
510(k) number:	K233596

IV. Device description

The product should be used in combination with SHINING3D printer. It is stored in 500ml HDPE bottle. 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
CB21-A1	A1
CB21-A2	A2
CB21-A3	A3
CB21-B1	B1

VII. Comparison to predicate devices

The Subject device and predicate device (K233596) share the same indication for use, material type, material shades, technology, curing method, performance standard requirements, while also exhibiting similarities such as the use of the printer device, post-cure device and chemical description. The similarities and differences have been evaluated and verified.

Additionally, the subiect device is indicated for use in artificial teeth applications, 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.

Item	Subject device	Predicate device	Comparison with Predicate Device
Product Name	Dura-Crown	VarseoSmile TriniQ	**N/A**
510(k) Number	/	K233596	**N/A**
Classification name	Tooth shade resin material	Tooth shade resin material	**Same**
Product Code	EBF, EBG, PZY	EBF, EBG, PZY	**Same**
Device Classification	Class II	Class II	**Same**
Submitter Name	Hangzhou SHINING3D Dental Technology Co., Ltd.	BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG	**N/A**

Item	Subject device	Predicate device	Comparison with Predicate Device
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.	VarseoSmile TriniQ is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The VarseoSmile TriniQ material is used for fabricating permanent restorations such as inlays, onlays, veneers, full crown and bridge restorations. VarseoSmile TriniQ can also be used for the fabrication of artificial teeth and temporary crowns & bridges.	**Same**

Item	Subject device	Predicate device	Comparison with Predicate Device
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	**Same**
Chemical Description	(Meth)acrylate oligomers and monomers, photo-initiator, fillers, additives and pigments.	VarseoSmile® TriniQ® is a ceramic-filled hybrid material consisting of (meth)acrylates, ceramic fillers, initiators, additives, and pigments	**Similar (Discussion A)**
Equipment	Validated 3D-Printer and post curing.	Validated 3D-Printer and post curing	**Substantial Equivalence**

Item	Subject device	Predicate device	Comparison with Predicate Device
Contraindication, warning	Do not use the product in case of a known allergy to one or more ingredients(such as acrylate).	VarseoSmile TriniQ is contraindicated in the case of known allergies to one or more ingredients. If in doubt, a specific test should be done before using this device to confirm or rule out the particular allergy. The material should not be used for purposes other than those described by the manufacturer. Any deviation from the intended purpose, the instructions for use or the design requirements for the specific purpose can have negative effects on the chemical and physical quality of the objects fabricated using the material.	**Substantial Equivalence**

Item	Subject device	Predicate device	Comparison with Predicate Device
Material Type	Methacrylate-based polymer resin	Methacrylate-based polymer resin	**Same**
Material Shades	Common VITA-shades	Common VITA-shades	**Same**
Biocompatible	Yes	Yes	**Same**
Sterile	Non-sterile	Non-sterile	**Same**
Curing Method	UV Light	UV light	**Same**
Shelf-Life	2 years	3 years	**Different**
Performance Testing	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	ISO 4049:2019 ISO 10477:2020 ISO 22112:2017	**Same**

Item	Subject device	Predicate device	Comparison with Predicate Device
Flexural Strength	⩾120MPa	⩾100MPa	**Different**
Biocompatibility Testing	ISO 10993-1:2018 ISO 7405:2018	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-17:2002 ISO 10993-18:2020 ISO 10993-23:2021 ISO/TS 21726:2019	**Similar**

VIII. Summary of Testing (Performance Data)：

Non-Clinical Performance Test Conclusion

Biocompatibility testing

According to clinical use of Dura-Crown, the duration in the human body is more than 30 days. According to the ISO 10993-1 and and ISO 7405 standard, the subject device is categorized as: Surface medical device - Mocosal membrane - long-term exposure(＞30 d). The Subject device was evaluated for:

- In Vitro Cytotoxicity Test
- Skin Sensitization Test
- Oral Mucosa Irritation Test
- Acute Systemic Toxicity Test
- Subacute Systemic Toxicity Test
- Subchronic Systemic Toxicity Test
- Subcutaneous Implantation Test
- Pyrogen Test
- AMES Test
- In vitro Mammalian Cell Chromosome Aberration Test

Performance Bench Testing:

Performance testing was conducted to verify that the subject device met all design specifications was Substantially Equivalent to the predicate device.

The test results demonstrated that the Dura-Crown complies with the following standards:

- 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

Shelf-Life:

The shelf life of the subject device is 2 years. The test was performed in accordance with ASTM F1980-21.

Clinical Test Conclusion:

No clinical study is included in this submission.

X. Conclusion

The subject device is as safe and effective as its predicate device. It shares the same indication for use, material type, material shades, technology, curing method etc.. 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.

Based upon the information presented in evaluation, the subject device is substantially equivalent to predicate device.