January 21, 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: K260170
Trade/Device Name: LumiCera
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: January 20, 2026
Received: January 20, 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 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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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)*
K260170

Device Name
LumiCera

Indications for Use *(Describe)*
LumiCera is used for fabricating permanent single crowns, permanent inlays and onlays, veneers, 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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K260170

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:	Yuzhuo Wang Title: Regulatory Affairs Specialist Phone: +86 15005173276 Email: wangyuzhuo@shining3d.com
Date Prepared:	January 16th, 2026

II Device

Device Name:	LumiCera
Model:	CB200-A1, CB200-A2, CB200-B1, CB200-BL, CB200-C2
Regulation Name:	Tooth shade resin material
Regulation Number:	21 CFR 872.3690
Regulatory Class:	Class II
Product Code:	EBF
Review Panel:	Dental

III Predicate Device

Trade/Device Name:	FREEPRINT® crown

Regulation Name:	Tooth shade resin material
Regulation Number:	21 CFR 872.3690
Regulatory Class:	Class II
Product Code:	EBF
Submitter Name:	DETAX GmbH
510(k) Number:	K222877

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

LumiCera is used for fabricating permanent single crowns, permanent inlays and onlays, veneers, bridges.

VI Available model and Specification

Model	Color
CB200-A1	A1
CB200-A2	A2
CB200-B1	B1
CB200-BL	0M2
CB200-C2	C2

Specification: 0.5 kg/bottle, Nano

VII Comparison to predicate devices

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

Item	Subject device	Predicate device	Remark
Product Name	LumiCera	FREEPRINT® crown	--
Regulation Name	Tooth shade resin material	Tooth shade resin material	Same
Product Code	EBF	EBF	Same
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	Same
Regulatory Class	Class II	Class II	Same

Item	Subject device	Predicate device	Remark
Indication for Use /Intended Use	LumiCera material is used for fabricating permanent single crowns, permanent inlays and onlays, veneers, bridges.	FREEPRINT® crown is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The FREEPRINT® crown material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of FREEPRINT® crown requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit.	Similar (Analysis 1)

Item	Subject device	Predicate device	Remark
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	Same
Materials	LumiCera is composed of methacrylate polymer resin with photo initiator, and pigments.	Methacrylate polymer resin with photo initiator, and pigments.	Same
Materials Shade	Common VITA-shades: A1, A2, B1, BL, C2	Common VITA-shades: A1, A2, A3, B1, B3, BL, C3, D3	Similar (Analysis 2)
Curing Method	UV Light，365~405 nm w/post curing	Visible light, 385 nm w/post curing	Similar (Analysis 3)
Equipment	Validated 3D-Printer and post curing devices.	Validated 3D-Printer and post curing devices	Same
Sterile	Non-sterile	Non-sterile	Same
Shelf-Life	2 years	2 years	Same

Item	Subject device	Predicate device	Remark
Performance Testing	ISO 4049:2019 ISO 10477:2020	ISO 4049:2019 ISO 10477:2020	Same
Depth of Cure	Hardness of bottom surface ≥70% top surface	Hardness of bottom surface ≥70% top surface	Same
Surface Finish	Glossy surface after polishing	Glossy surface after polishing	Same
Flexural Strength	≥ 100 MPa	≥ 100 MPa	Same
Water Sorption	≤ 40 μg/mm^3	≤ 40 μg/mm^3	Same
Water 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 Discussion for similarities

Analysis 1. Indication for Use/Intended Use

Both subject devices and predicate devices can be used to manufacture permanent single crowns, permanent inlays and onlays, veneers, and bridges with same manufacturing processes. Predicate devices have a wider range of intended use compared to subject devices. The minor difference does not influence substantial equivalence.

Analysis 2. Materials Shade

The different color due to the composition in the content of pigments. These color variations do not raise new questions of safety or effectiveness, as both devices meet the required performance and biocompatibility standards. Therefore, the differences in color do not impact the substantial equivalence of the subject device to the predicate device.

Analysis 3. Curing Method

The Subject and Predicate devices are both photo-curable polymer resins. Photo-curable polymer resins exhibit similar free radical polymerization efficiency among 365 nm ~405nm light regions. Slight differences in the curing light wavelength do not influence substantial equivalence.

IX 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

Bench Testing:

Physical and mechanical properties of the subject device were evaluated according to FDA-recognized version ISO 4049 Dentistry - Polymer-based restorative materials and ISO 10477 Dentistry - Polymer-based crown and veneering materials.

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.

Sterility and Shelf-Life Testing:

The device is provided non-sterile.

From the Shelf-life testing, LumiCera has a shelf life of 2 years.

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. The subject device has similar intended use, and same material, technology and performance characteristics.

The minor differences among the subject device and predicate devices 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. LumiCera is substantially equivalent.