March 31, 2025

Hangzhou SHINING3D Dental Technology Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K250946
Trade/Device Name: Denture Base Resin DT20
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI
Dated: March 28, 2025
Received: March 28, 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)*
K250946

Device Name
Denture Base Resin DT20

Indications for Use *(Describe)*
Denture Base Resin is a light-curable polymerizable resin intended to be used for the fabrication of full and partial removable dentures. Fabrication of denture bases with Denture Base Resin requires a digital denture file, 3D printer and post-curing unit.

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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K250946

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
Contact person:	Name: Yuzhuo Wang Title: Regulatory Affairs Specialist Phone: +86 15005173276 Email: wangyuzhuo@shining3d.com
Date Prepared:	February 15, 2025

II Subject Device

Trade Name of Device:	Denture Base Resin DT20
Common Name	Denture Base Resin
Classification Name(s):	Resin, Denture, Relining, Repairing, Rebasing
Model:	DT20-OR, DT20-LRP, DT20-LT
Regulation Number:	21 CFR 872.3760
Product Code:	EBI
Regulatory Class	Class II
Submission number:	

III Predicate Device

Trade name:	NextDent Denture 3D+
Common and Classification Name(s):	Resin, Denture
Classification:	21 CFR 872.3760
Regulatory class:	Class II
Product code:	EBI
Submitter Name:	Vertex-Dental B.V.
510(k) number:	K191497

IV Device description

Denture Base Resin is a liquid light-curable material. The product should be used in combination with the 3D printer. Printer and resin must be optimized to each other in order to get complete and precise printed parts. The 3D printer and the post-curing

unit of SHINING3D make use of a light source to polymerize the Denture Base Resin.

3D Printer	
Brand	Model
SHINING 3D	AccuFab-D1s, AccuFab-C1s
Post-curing Unit	
Brand	Model
SHINING 3D	FabCure 2

The 3D printer and the post-curing unit of SHINING3D are not included with the device.

V Intended Use /Indications for use

Denture Base Resin is a light-curable polymerizable resin intended to be used for the fabrication of full and partial removable dentures. Fabrication of denture bases with Denture Base Resin requires a digital denture file, 3D printer and post-curing unit.

VI Available model

Model	Color Code
DT20-OR	OR
DT20-LRP	LRP
DT20-LT	LT

VII Comparison to predicate devices

Item	Subject Device	Predicate device (K191497)	Discussion
Product Name	Denture Base Resin DT20	**NextDent Denture 3D+**	/
Classification	Class II	Class II	Same
Product Code	EBI	EBI	Same
Regulation	21 CFR 872.3760	21 CFR 872.3760	Same
Indications for Use/Intended Use	Denture Base Resin is a light-curable polymerizable resin intended to be used for the fabrication of full and partial removable dentures. Fabrication of denture bases with Denture Base Resin requires a digital denture file, 3D printer and post-curing unit.	NextDent Denture 3D+ is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. NextDent Denture 3D+ is intended exclusively for professional dental work. Fabrication of denture bases with NextDent Denture	Similar Both the subject and predicate devices are alternatives to traditional heat cured and auto polymerization resins， and are light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The predicate device uses a scanner in order to obtain digital denture files, same as the subject device.

Item	Subject Device	Predicate device (K191497)	Discussion
		3D+ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following scanner, design software, additive printer and post-cure unit： Design: Brand / Type / Software Scanner: 3Shape / D900 Design software: 3Shape / Dental-System 2016 Premium Printing: Brand / Type / Software Printer: 3D Systems / NextDent 5100 Figure4® / 3D Sprint Post-curing: Brand / Type / Software Post-cure unit: NextDent / LC-3DPrint Box / n.a.	Thus, the intended use of the subject and predicate devices is substantially the same.
Printer Device	AccuFab-D1s，AccuFab-C1s	NextDent 5100 Figure 4®	Similar Compatible printer types have been verified for the subject device.
Post-curing Device	FabCure 2	LC- 3D Print Box	Similar Compatible post-curing device types have been verified for the subject device.

Item	Subject Device	Predicate device (K191497)	Discussion
Material Composition	Methacrylate-based resins, photo-initiator and pigments.	Methacrylate-based resins with photo-initiator, filler and pigments.	Similar Compared to predicate devices, subject devices have no filler. The filler is used to adjust the mechanical properties, as can acrylates. And the subject equipment passes a bench test that shows that the performance meets the standard requirements.
Material Type	Light-curable Resin	Light-curable Resin	Same
Curing Method	UV Light	UV Light	Same
Product State	Liquid	Liquid	Same
Manufacturing Technology Type	Additive	Additive	Same
Shelf-Life	2 years	2 years	Same
Environment of Use	Healthcare facility/hospital Dental (technical) laboratory.	Healthcare facility/hospital Dental (technical) laboratory.	Same
Sterility	Non-sterile	Non-sterile	Same
Performance Testing	Meets the performance standards for Type 4 denture base polymer per ISO	Meets the performance standards for Type 4 denture base polymer per ISO	Same

Item	Subject Device	Predicate device (K191497)	Discussion
	20795- 1.	20795- 1.	
Biocompatibility Testing	Denture Base Resin is considered a surface device, in contact with the mucosal membrane, for > 30 days. Tested to ISO 7405, ISO 10993-1 Cytotoxicity (Part 5) Sensitization (Part 10) Irritation (Part 23) Subacute/subchronic systemic toxicity (Part 11) Genotoxicity (Part 3) Acute systemic toxicity (Part 11) Pyrogen Test (Part 11) Implantation (Part 6)	NextDent™ Denture 3D+ is considered a surface device, in contact with the mucosal membrane, for > 30 days. Tested to ISO 10993-1 Cytotoxicity (Part 5) Sensitization (Part 10) Irritation or intracutaneous reactivity (Part 10) Subacute/subchronic systemic toxicity (Part 11) Genotoxicity (Part 3)	Similar The subject device takes into account the applicable ISO 7405 standard. Based on ISO 10993-1 and ISO 7405, acute systemic toxicity, pyrogen and implantation tests are included.

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 Surface device in contact with mucosal membrane with permanent contact (>30 d). The subject device was evaluated for:

Cytotoxicity

Sensitization

Irritation

Acute systemic toxicity

Subacute/subchronic systemic toxicity

Implantation

Material-mediated pyrogenicity

Genotoxicity

Performance Bench Testing:

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

The test results demonstrated that the Denture Base Resin complies with the following standards:

- ISO 20795-1: 2013 Dentistry—Base polymers —Part 1: Denture base polymers
- ISO 7491: 2000 Dental materials-Determination of color stability.

Shelf-Life:

The shelf life of the Denture Base Resin is 2 years. The test was performed in accordance with ASTM F1980-16.

Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The Denture Base resin is as safe and effective as its predicate device. The Denture Base Resin has similar intended use and technological characteristics. The minor differences between the Denture Base Resin and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Denture Base Resin is as safe and effective as the predicate device. Thus, the Denture Base Resin is substantially equivalent.