May 6, 2026

Shandong Huge Dental Material Corporation
Zheng Maggie
Regulatory Affairs Manager
68 Shanhai Rd., Donggang District
Rizhao City, 276800
CHINA

Re: K260376
Trade/Device Name: Denture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: February 5, 2026
Received: February 5, 2026

Dear Zheng Maggie:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K260376

Device Name
Denture Base

Indications for Use *(Describe)*
Denture Base is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. Denture Base can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures. Denture Base can be utilized as an aid in bonding the denture teeth onto denture base.

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 K260376

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** May 05, 2026

2. **Submitter Information:**

Owner's Name	Shandong Huge Dental Material Corporation
Address	No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China
Telephone	0086 633 2277268
Fax	0086 633 2277298
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: Denture Base

Common name: Denture Base

Classification name: Denture relining, repairing, or rebasing resin (21 CFR 872.3760)

Regulatory Class: Class II

Product Code: EBI

4. **Predicate and Reference Device Information**

Owner/Operator	Device Name	510 (k) No.	Product Code	Remarks
Dentca, Inc.	Dentca Base Premium, Dentca Base Hi-Impact	K220042	EBI	Primary predicate device
SPRINTRAY INC.	Apex Base (Light Pink, Original Pink, Dark Reddish Pink, Opaque Original Pink); High Impact Denture Base (Light Pink, Original Pink, Dark Pink, Light Meharry, Original Meharry, Bubblegum)	K221678	EBI	Secondary predicate device

Note: The secondary device is included to facilitate a comparative analysis of technological characteristics, thereby establishing a basis for determining the substantial equivalence of the subject device to legally marketed devices.

5. Description of Device

Fabrication of dental prosthetics with Denture Base resin requires computer-aided design and manufacturing system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, 3D printer, and curing light equipment. The Denture Base consists of a curable dental acrylate resin that is designed to be used in conjunction with a scanned 3D image of a patient's teeth, and 3D printer assembly, to locally manufacture out a dental appliance in dental offices based on the clinician's judgment of patient need.

The Denture Base product operates on the principle of photoactivated polymerization to transform a malleable resin into a rigid, functional dental prosthesis. A software-driven 3D printer solidifies the liquid resin layer-by-layer through precise light exposure to build the final denture base geometry.

The Denture Base product family comprises a single device model (DB) offered in multiple shades. All variants are identical in their fundamental composition (methacrylate-based resin, photoinitiator, filler and color pastes/pigments), manufacturing process, and core technical performance specifications.

6. Indications for Use

Denture Base is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. Denture Base can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures. Denture Base can be utilized as an aid in bonding the denture teeth onto denture base.

7. Technological Characteristics Comparison

The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate devices:

Feature	Subject device	Primary Predicate device	Secondary Predicate device	Conclusion
	K260376 Denture Base	K220042 Dentca Base Premium, Dentca Base Hi-Impact	K221678 Apex Base (Light Pink, Original Pink, Dark Reddish Pink, Opaque Original Pink); High Impact Denture Base (Light Pink, Original Pink, Dark Pink, Light Meharry, Original Meharry, Bubblegum)	
Product Code	EBI	EBI	EBI	Same
Regulation	21 CFR 872.3760	21 CFR 872.3760	21 CFR 872.3760	Same
Indications of Use	Denture Base is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. Denture Base can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures. Denture Base can be utilized as an aid in bonding the denture teeth onto denture base.	DENTCA Base Resin is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. DENTCA Base Resin can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures. Fabrication of these prostheses with DENTCA Base Resin requires a digital denture file, additive printer, and curing light equipment. DENTCA Base Resin can be utilized as an aid in bonding the denture teeth onto denture base.	The SprintRay High Impact Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair, of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.	Similar[1]
Main Composition	Methacrylate-based resin	Methacrylate-based resin	Methacrylate-based resin	Similar
Material Type	Light-curable Resin	Light-curable Resin	Light-curable Resin	Similar
Curing Method	UV Light	UV Light	UV Light	Similar
Physical Form	Liquid	Liquid	Liquid	Same

Feature	Subject device	Primary Predicate device	Secondary Predicate device	Conclusion
	K260376 Denture Base	K220042 Dentca Base Premium, Dentca Base Hi-Impact	K221678 Apex Base (Light Pink, Original Pink, Dark Reddish Pink, Opaque Original Pink); High Impact Denture Base (Light Pink, Original Pink, Dark Pink, Light Meharry, Original Meharry, Bubblegum)	
Manufacturing Technology Type	Additive	Additive	Additive	Same
Shelf life	18 months	3 years	1.5 years	Same
Prescription/over-the-counter use	Prescription	Prescription	Prescription	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Package form	bottle	bottle	bottle	Same
Physical Properties	The subject device and predicate devices have substantially equivalent physical properties as they all conform to the applicable specifications set in ISO 20795-1 for Type 4 material.			Similar[2]
Biocompatibility	Biocompatible. The subject device and predicate devices meet the applicable requirements of ISO 7405 and ISO 10993 standards.			Similar
Additive Manufacturing	Testing, according to FDA's guidance Technical Considerations for Additive Manufactured Medical Devices, was performed and results were provided in the 510(k). These tests included evaluation of all relevant properties of the printed resin using the permitted machines. Further, tests based on considerations of the orientation during manufacturing were performed.			Similar

Note[1]: The subject device and the predicate devices have substantially the same indications for use. The minor differences in indications for use concerning try-in dentures and bonding do not affect the determination of substantial equivalence, as these differences represent a logical and clinically necessary extension of the device's fundamental purpose as a denture base resin—a purpose that is fully aligned with that of the legally marketed primary predicate device (K220042).

Note[2]: The subject device was compared to the secondary predicate device(K221678) for technological characteristics. Testings were performed per ISO 20795-1 and internal standards, and the test results demonstrate that the subject device is substantially equivalent to the legally marketed predicate device(K221678) with respect to all key technological and physicochemical properties.

8. Summary of Non-clinical testing

The physical properties of the subject device were determined according to ISO 20795-1 and internal standard. Bench testings were performed on the subject device and the secondary predicate device, the test results demonstrated the substantial equivalence when compared to the secondary predicate device. The main test items including: Homogeneity, Surface characteristics, Colour, Colour stability, Translucency, Freedom from porosity, Ultimate flexural strength, Flexural modulus, Maximum stress intensity factor for materials with improved impact resistance, Total fracture work, Bonding to synthetic polymer teeth, Sorption, Solubility, Residual methyl methacrylate monomer, Polishing performance, Dimensional Accuracy, Anisotropy (Post-curing).

Additionally, the compositions of the subject device do not contain any non-conventional chemicals compared to the legally marketed predicate devices. Biocompatibility tests were performed fully following the ISO 7405 and ISO 10993 standards, to demonstrate substantial equivalence to the predicate device in terms of biocompatibility, including Cytotoxicity, Skin sensitization, Irritation, Acute systemic toxicity, Subchronic systemic toxicity and Genotoxicity.

As per FDA guidance "Technical Considerations for Additive Manufactured Medical Devices", 3D Printing Parameters and Cleaning Verification was performed to verify 3D printing parameters, leftover material reuse, post-processing cleaning parameters, post-curing light parameters, and 3D printer compatibility of the subject device through systematic experiments, ensuring the matching and stability of the parameters.

9. Clinical Performance Data

Clinical test is not applicable.

10. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the subject device has demonstrated substantial equivalence. Shandong Huge Dental Material Corporation concludes that the subject device is substantially equivalent to the predicate devices described herein.