



August 12, 2022

Shandong Huge Dental Material Corporation  
Maggie Zheng  
Regulatory Affairs Manager  
No. 68 Shanhai Road, Donggang District  
Rizhao City, Shandong 276800  
China

Re: K220680

Trade/Device Name: Denture Base Polymers  
Regulation Number: 21 CFR 872.3760  
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin  
Regulatory Class: Class II  
Product Code: EBI  
Dated: April 27, 2022  
Received: May 2, 2022

Dear Maggie Zheng:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.  
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

## Indications for Use

510(k) Number (if known)  
K220680

Device Name  
Denture Base Polymers

Indications for Use (Describe)

Denture Base Polymers is used for fabrication and repair of partial and full denture base for patients with missing teeth.

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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## 005\_510 (k) Summary K220680

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

### 1. Date Summary Prepared: July 20, 2022

### 2. Submitter Information:

Name Shandong Huge Dental Material Corporation  
Address No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong  
Province, 276800, P.R. China  
Telephone 086-633-2277268  
Contact Person Ms. Maggie Zheng  
Contact Title Regulatory Affairs Manager  
E-mail zhengxy@hugedent.com

### 3. Device Name

Trade name: Denture Base Polymers  
Common name: Dental base material  
Classification name: resin, denture, relining, repairing, rebasing (21 C.F.R. 872.3760)  
Regulatory Class: II  
Product Code: EBI

### 4. Substantially Equivalent Device

Company Name	Device Name	510 (k) NO.	Substantially Equivalent (SESE) Decision Date	Product code	Remarks
VERTEX-DENTAL BV	Vertex Rapid Simplified	K102654	12/03/2010	EBI	Primary Predicate
VERTEX-DENTAL BV	Vertex Self Curing, Vertex Castavaria, Vertex Castapress	K102640	03/25/2011	EBI	Secondary Predicate

These predicate devices have not been subject to a design-related recall.

### 5. Description of Device

Denture Base Polymers contains powder and liquid, wherein the powder is mainly composed of polymethyl methacrylate, and the main composition of the liquid is methyl methacrylate.

Denture Base Polymers is used for fabrication and repair of partial and full denture base for patients with missing teeth, and its extensive indications can meet the needs of the production of complete denture.

## 6. Indications for use

Denture Base Polymers is used for fabrication and repair of partial and full denture base for patients with missing teeth.

## 7. Summary of Physical and Chemical Properties Tests

- Chemical Composition:

The device has similar chemical composition as the predicate devices. All of them are mainly composed of Polymethyl methacrylate and Pigments (Powder) and Methyl methacrylate, Ethyleneglycol dimethacrylate (Liquid).

- Technological characteristics:

The device has the same technological characteristics as the predicate devices (Heat Curing and Self Curing). And the device is similar in specifications and shades as the predicate devices.

- Properties:

The device has comparable physical and chemical properties as the predicate devices.

(Meeting the requirements of ISO standards for the Dental base material, ISO 20795-1)

- Applications:

The device has similar indications for use as the sum of the predicate devices: fabrication and repair of partial and full denture base.

## 8. Technological Characteristics:

The new device, Denture Base Polymers, has the same design, main materials and chemical composition as the predicate device.

Comparison Items	New Device	Primary Predicate	Secondary Predicate
		Denture Base Polymers K220680	Vertex Rapid Simplified K102654
1) Regulatory Classifications	same	same	same
2) Indications for use	This product is used for fabrication and repair of partial and full denture base for patients with missing teeth.	The Vertex Rapid Simplified is indicated for: 1. Fabrication of full dentures 2. Fabrication of partial dentures	Vertex cold-curing denture base materials are indicated for: 1. Manufacture of full and partial dentures 2. Repair of full and partial dentures 3. Rebasing of full and partial dentures 4. Relining of full and partial

Comparison Items	New Device		Primary Predicate				Secondary Predicate			
	Denture Base Polymers K220680		Vertex Rapid Simplified K102654				Vertex Self Curing, Vertex Castavaria, Vertex Castapress K102640			
3) Contraindications	NA		NA				dentures NA			
4) Composition of Materials	PMMA, MMA, EDMA		PMMA, MMA, EDMA				PMMA, MMA, EDMA			
5) Physical Properties	Physical parameters		Flexural strength	Water absorption	Solubility		Residual methyl methacrylate monomer		Flexural modulus	
			Type 1: $\geq 65$ MPa Type 2: $\geq 60$ MPa	$\leq 32$ ug/mm <sup>3</sup>	Type 1: $\leq 1.6$ ug/mm <sup>3</sup> Type 2: $\leq 8.0$ ug/mm <sup>3</sup>		Type 1: $\leq 2.2\%$ Type 2: $\leq 4.5\%$		Type 1: $\geq 2000$ MPa Type 2: $\geq 1500$ MPa	
	New Device	Type 1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	
		Type 2	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	
	Primary Predicate (K102654)		Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	
Secondary Predicate (K102640)		Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1	Meet the criteria per ISO 20795-1		
6) Labeling	similar		similar				similar			
7) Target Population	dental patients		dental patients				dental patients			
8) Anatomical Site	on teeth		on teeth				on teeth			
9) Where Used	used in hospital, dental clinic and relevant places		used in hospital, dental clinic and relevant places				used in hospital, dental clinic and relevant places			
10) Human Factors	dental professional		dental professional				dental professional			
11) Design	same		same				same			
12) Cautions	similar		similar				similar			
13) Standards Met	same		same				same			
14) Biocompatibility	biocompatible		biocompatible				biocompatible			
15) Sterility	Non-sterile		Non-sterile				Non-sterile			
16) Chemical Safety	similar		similar				similar			

## 9. Summary of Biocompatibility

The new device, Denture Base Polymers, is substantially equivalent to the predicate devices that have been on the market for years and with no clinical adverse events. The formulation of new device does not contain any new or non-conventional chemicals compared to the legally marketed predicate device.

We selected our Denture Base Polymers (Model: Type 2 Class 1) as the representative in biocompatibility tests and those biocompatibility test reports can be used in the biological evaluation of Denture Base Polymers.

Biocompatibility tests were performed fully following the ISO 10993 standards. The test items include Cytotoxicity; Sensitization; Irritation or Intracutaneous Reactivity; Acute Systemic Toxicity; Material-Mediated Pyrogenicity; Subchronic Toxicity; Genotoxicity and Implantation.

## **10. Clinical Performance Data**

Not applicable. Clinical performance testing has not been performed on the subject device.

## **11. Summary of Substantial Equivalence**

As with the comparison shown in substantial equivalence discussion, these devices are same or similar in almost all aspects. The details of indications for use, composition of materials, physical properties, labeling, stability/shelf life and cautions are slightly different, but the minor differences between the new device and the predicate devices are out of significance and do not affect neither the general intended use nor substantial equivalence.

We conclude that our Denture Base Polymers is substantially equivalent to the predicate devices described herein.