September 24, 2020

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

Re: K201684
Trade/Device Name: A-Silicone for Bite Registration
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: June 15, 2020
Received: June 22, 2020

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinvas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201684

Device Name
A-Silicone for Bite Registration

Indications for Use *(Describe)*
A-Silicone for Bite Registration is indicated for making occlusal registrations.

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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K201684

510 (k) Summary

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:** September 24, 2020

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	086-633-2277285
Fax	086-633-2277298
Contact Person	Mrs. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: A-Silicone for Bite Registration

Common name: Bite Registration

Classification name: Impression material (21 CFR 872.3660)

Regulatory Class: II

Product Code: ELW

4. **Predicate Device Information**

Table 1: Predicate Device Information

Owner/Operator	Device Trade Name	510 (k) No.	Product Code	Predicate
Zhermack S. P. A.	Occlufast Rock	K024034	ELW	Primary

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

No reference devices were used in this submission.

5. **Description of Device**

A-Silicone for Bite Registration is a vinylpolysiloxane (addition silicone), also known as A-Silicones, polyvinyl siloxanes (PVS), or vinyl polysiloxanes (VPS), especially made for bite registration work in the surgery and laboratory. It mainly contains polydimethylsiloxane, silica and platinum catalyst.

6. Indications for Use

A-Silicone for Bite Registration is indicated for making occlusal registrations.

7. Technological Characteristics

All components of the A-Silicone for Bite Registration are based upon industry well-known chemistry. A-Silicone for Bite Registration is vinylpolysiloxane based materials which has two components addition-type (platinum-catalyzed) silicone rubber. If two parts were mixed together, it will transform into elastomeric materials by the platinum-catalyzed addition curing reaction.The following table shows the technological characteristics for the subject device and indicates the following similarities and differences with the predicate device:

Table 4: Technological Characteristics Comparison Table

Technological Characteristics	Subject device (A-Silicone for Bite Registration)	Primary predicate device (Occlufast Rock, K024034)
Description of Material	Vinylpolysiloxane based	Vinylpolysiloxane based
Mode of Action	Addition-curing bite registration	Addition-curing bite registration
Indications of Use	A-Silicone for Bite Registration is indicated for making occlusal registrations.	Zhermack OCCLUFAST ROCK a dental impression material intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.
Prescription/over-the-counter use	Prescription	Prescription
Physical Form	Double cartridge system 1:1	Double cartridge system 1:1
Accessories	Mixing tips, Dispenser	Mixing tips, Dispenser
Physical Properties		

	HUGE	ZHERMACK	Remarks
Trade name	A Silicone For Bite Registration	Occlufast Rock	/
Consistency (≤35mm)	20mm	23mm	Similar
Linear dimensional change （≤1.5%）	- 0.2%	- 0.2%	Same

Table 4: Technological Characteristics Comparison Table				
Technological Characteristics	Subject device (A-Silicone for Bite Registration)		Primary predicate device (Occlufast Rock, K024034)	
	Detail reproduction （75μm）	75μm	75μm	Same
	Elastic recovery （≥96.5%）	99%	99%	Same

The subject device and primary predicate device have minor different Indications for Use language. However, the difference in language does not change the intended use or substantial equivalence, both products are intended for bite registration work in the surgery and laboratory. Besides, other comparison items such as description of material, mode of action, physical form, accessories and physical properties, etc. are the same. And both products are supplied for prescription use.

8. Summary of Non-clinical performance testing

Physical properties testing

A-Silicone for Bite Registration has similar physical and chemical properties as the predicate devices. A-Silicone for Bite Registration was tested and met the applicable requirements of the FDA Recognized Consensus standard: ISO 4823 Fourth edition 2015-08-01 Dentistry - Elastometric impression materials.

Summary of Physical Properties Testing			
Items	Requirements per ISO 4823	Requirements of our company and Pre-test planning approaches and test methods of our company	Test Conclusion
Component colours	Different components intended for use in the same mixture shall be supplied in contrasting colours to provide a means of determining when the components have been thoroughly mixed.	Same as ISO 4823	Satisfactory
Consistency	≤35mm	Same as ISO 4823	Satisfactory
Linear dimensional change	≤1.5%	Same as ISO 4823	Satisfactory
Detail reproduction	75μm	Same as ISO 4823	Satisfactory
Elastic recovery	≥96.5%	Same as ISO 4823	Satisfactory

Biocompatibility testing

The subject device, A-Silicone for Bite Registration, is substantially equivalent to the predicate device that have been legally marketed for decades and with no clinical adverse events. The formulation of the subject device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

Biocompatibility tests were performed fully following the ISO 10993 standards. The test items include Cytotoxicity, Sensitization and Irritation.

9. Clinical Performance Data

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

10. Conclusions

Based on the indications for use, technological characteristics, performance testing and other information provided in this premarket notification, the subject device has been shown to be safe and effective for its intended use and the minor differences in indications for use fall within the intended use of the predicate device affecting neither the general intended use nor substantial equivalence. Shandong Huge Dental Material Corporation concludes that the subject device is substantially equivalent to the predicate device described herein.