December 27, 2024

Beijing OKVD Biological Technology Ltd.
℅ Helen Nan
Manager
New Risen Enterprise Management Consulting Co.,Ltd
Room302, Building 3, Hangqian Mansion, Hangqian Street
Wenzhou, Zhejiang 325000
China

Re: K241924
Trade/Device Name: Elastic Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: July 1, 2024
Received: July 1, 2024

Dear Helen Nan:

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,

Bobak Shirmohammadi -S

For 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.

Submission Number *(if known)*

K241924

Device Name

Elastic Impression Material

Indications for Use *(Describe)*

An addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K241924
(As required by 21 CFR 807.92(a))

1.0 Submitter Information

· Company: Beijing OKVD Biological Technology Ltd.
· Address: Room 602, 6th Floor, Building 9, No. 22 Linhe Street, Linhe Economic Development Zone, Shunyi District, Beijing, China 101399
· Phone: 13601210227
· Email: zhangxianghao@okdental.cn
· Contact: Zhang Xianghao
· Date: June 1st 2024

2.0 Device Information

· Trade Name: OK Dental
· Proprietary Name: Elastic Impression Material;
· Classification: Device Class: 2
Review Panel: Dental
Regulation Description: Impression Material.
Regulation Number: 21 CFR 872.3660
Product Code: ELW

· Predicate Device:
K133071 submitted by Rizhao Huge Dental Industry Co., Ltd

3.Device Description:

The product is a kind of addition-cure silicon rubber impression material composed of vinyl polysiloxane and various fillers,with neutral smell and applicable to impression in dentistry. This product is mainly composed of a matrix and a catalyst. The matrix is mainly composed of polydimethylsiloxane, vinyl silicone oil, methyl hydrogen polysiloxane, silica dioxide, ,calcium carbonate, and colorants. The catalyst is mainly composed of polydimethylsiloxane, silica dioxide, calcium carbonate, platinum catalyst, and colorants.

4.Indication for Use:

An addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

5.Comparison of Required Technology Characteristics:

Item	Predicate DeviceK	Subject Device	Significant Differences
510k	K133071	K241924	
Company Name	Rizhao Huge Dental Industry Co.,Ltd	Beijing OKVD Biological Technology Ltd.	
Product Name	A Silicone Dentistry-Elastic Impression Material;	Elastic Impression Material;	difference
Indication for Use	An addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant	An addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant	same

	impression techniques.	impression techniques.	
Mode of Use	1.OK Dental Light body/Regular body wash: A very hydrophilic impression material used in heavy/wash or putty/wash impression procedures and capable of capturing extraordinary sub-gingival details. It is used in crown and bridge and all high precision applications. 2.PEFIT Regular body: A regular impression material with superior mechanical strength used in single step impression procedures such mouth guards, night guards, orthodontic, and edentulous applications. 3.OK Dental Heavy Body: A heavy body impression material combining strength, elasticity and dimensional stability to deliver the most accurate impressions. It is used in two-step heavy-wash applications such as for crown and bridge procedures.	1.OK Dental Light body/Regular body wash: A very hydrophilic impression material used in heavy/wash or putty/wash impression procedures and capable of capturing extraordinary sub-gingival details. It is used in crown and bridge and all high precision applications. 2. OK Dental Regular body: A regular impression material with superior mechanical strength used in single step impression procedures such mouth guards, night guards, orthodontic, and edentulous applications. 3.OK Dental Heavy Body: A heavy body impression material combining strength, elasticity and dimensional stability to deliver the most accurate impressions. It is used in two-step heavy-wash applications such as for crown and bridge procedures.	same
Principles of Operation	OK Dental is a dental impression that takes imprints of hard (teeth) and/or soft tissues. It captures a part or all of a person's dentition and surrounding structures of oral cavity. The dental impression forms an imprint (i.e. a 'negative' mold) of teeth and soft tissues, which can then be used to make a cast of the dentition. An impression is made by placing a viscous, thixotropic impression material into the mouth via a dental impression tray. The material, then sets to become an elastic solid, and, when removed from the mouth, provides a detailed and stable negative of teeth.	OK Dental is a dental impression that takes imprints of hard (teeth) and/or soft tissues. It captures a part or all of a person's dentition and surrounding structures of oral cavity. The dental impression forms an imprint (i.e. a 'negative' mold) of teeth and soft tissues, which can then be used to make a cast of the dentition. An impression is made by placing a viscous, thixotropic impression material into the mouth via a dental impression tray. The material, then sets to become an elastic solid, and, when removed from the mouth, provides a detailed and stable negative of teeth.	same
Shelf-life	3 years	2 years	difference
Safety&Effectiveness	Tested according to FDA recognized standards - ISO 10993-3、ISO10993-5、ISO10993-10 and ISO 4823	Tested according to FDA recognized standards: - ISO 10993-5、ISO10993-10、ISO10993-23 and ISO 4823	same
NOTE: ISO10993-23 is an upgrade of ISO10993-3			

The type in Report	TYPE3	TYPE 0	difference
the product submitted for inspection adopts Type 0 type product, which is based on the requirements of the ISO4823 standard, which divides this product into 0, 1, 2 and 3 type products, and the difference between these 4 types is mainly in the difference of "consistency" index, and its chemical properties and biological evaluation requirements are consistent, and the Type 0 silicone rubber with the largest consistency is fully representative.			
Brief Summary: First, the subject device - OK Dental(Elastic Impression Material) incorporates the same intended use with the predicate device. Secondly, the subject device shares almost the same design and fundamental technological characteristics with the predicate device, for example: the same principle of operation and mode of use. Thirdly, both their safety and effectiveness have been verified by appropriated standards, thus being equally safe and effective. Though they are different in shelf-life, such different will not affect the core usage of the device, thus will not influencing the comparison of substantial equivalence between the two devices.			

6.Discussion of Tests Performed

· Clinical Tests:

Clinical testing has not been conducted on this product.

· Non-Clinical Tests

The subject device was tested to evaluate its safety and effectiveness according to the following standards:

- Biocompatibility Test according to

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation。

ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.

- Device Effectiveness according to ISO 4823： 2021

7. Conclusion:

First, the subject device - OK Dental(Elastic Impression Material) enjoys the same intended use and similar technological characteristics with the predicate device. Besides, the performance safety and effectiveness of the subject device has been verified in accordance with the above FDA recognized standards, thus being considered to be as safe and effective as the predicate device.

In a word, it is reasonable for us to conclude that the subject device is substantially equivalent to the predicate device according to the above analysis.