March 4, 2022

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

Re: K213994
Trade/Device Name: Flexible Block
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, MQC
Dated: December 15, 2021
Received: December 21, 2021

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 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

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)*
K213994

Device Name
Flexible Block

Indications for Use *(Describe)*
Intended for making dental plates, bite plates, frame-works, clasps,personal trays, appliances, occlusal splints and night guards.

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

K213994

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

1. **Date Summary Prepared:** Feb. 18, 2022

2. **Submitter Information:**

Name	Shandong Huge Dental Material Corporation
Address	No. 68 Shanghai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China
Telephone	086-633-2277268
Fax	086-633-2277298
Contact Person	Ms. Maggie Zheng
Contact Title	Regulatory Affairs Manager
E-mail	zhengxy@hugedent.com

3. **Device Name**

Trade name: Flexible Block

Common name: Dental polymer blanks (discs or blocks)

Classification name: Resin, Denture, Relining, Repairing, Rebasing (21 C.F.R. 872.3760)

Regulatory Class: II

Product Code: **EBI**, MQC

4. **Substantially Equivalent Device**

Company Name	Device Name	510 (k) NO.	Substantially Equivalent (SE) Decision Date	Product code
PERFLEX	Perflex Biosens	K150454	05/26/2015	**EBI**, MQC

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

5. **Description of Device**

Flexible Block is a circular solid (disc) or rectangular solid (block) made from polyamide through high-temperature injection molding, and is used in a CAD/CAM milling machine for production of dental plates, bite plates, frame-works, clasps, personal trays, appliances, occlusal

splints and night guards. These blocks are available in a variety of shapes and sizes for different milling systems and in a variety of dental shades.

6. Intended use

Patient populations: Patients need dental restorations in dental therapy.

Target user group: Use by health care professional or dentist.

Indications for use: Intended for making dental plates, bite plates, frame-works, clasps, personal trays, appliances, occlusal splints and night guards.

7. Summary of Physical and Chemical Properties Tests

- Chemical Composition:

The device is made from polyamide.

- Technological characteristics:

The device has the same technological characteristics as the predicate device (Perflex Biosens). And the device is similar in sizes, shapes and shades as the predicate devices.

- Properties:

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

- Applications:

The device has similar indications for use as the sum of the predicate devices: Intended for making dental plates, bite plates, frame-works, clasps,personal trays, appliances, occlusal splints and night guards by CAD/CAM.

8. Technological Characteristics:

The new device, Flexible Block, has the same design, materials and chemical composition as the predicate device.

Bench tests were performed on the new device including the items listed in the table below. The test results indicated that the new device meets the pass/fail criteria and supports substantial equivalence when compared to the predicate device on physical properties.

Comparison Items	**New Device**	**Predicate Device**
	Flexible Block	Perflex Biosens K150454
1) Regulatory Classifications	same	same
2) Indications for use	similar	similar
3) Contraindications	same	same
4) Composition of Materials	Polyamide	super polyamide, thermoplastic compound

Comparison Items	New Device							Predicate Device
	Flexible Block							Perflex Biosens K150454
5) Physical Properties	Physical parameters	Tensile strength: ≥30Mpa	Elongation at break: ≥40%	Water absorption: ≤5%	Impact strength: ≥20KJ/m2	Flexural strength: ≥30Mpa	Flexural modulus: ≥1000Mpa	
	Inspection method basis	ASTM D638	ASTM D638	ASTM D570	ASTM D256	ASTM D790	ASTM D790	
6) Labeling	similar							similar
7) Target Population	dental patients							dental patients
8) Anatomical Site	on teeth							on teeth
9) Where Used	used in hospital, dental clinic and relevant places							used in hospital, dental clinic and relevant places
10) Human Factors	dental professional							dental professional
11) Design	Circular solid (disc) or rectangular solid (block) of polyamide.							Circular solid (disc) or rectangular solid (block) of super polyamide and thermoplastic compound.
12) Cautions	similar							similar
13) Standards Met	same							same
14) Biocompatibility	ISO 10993-3 Non genotoxocity ISO 10993-5 Non cytotoxicity ISO 10993-10 Non sensitization or irritation ISO 10993-11 Non systemic toxicity							NA
15) Sterility	Non-sterile							Non-sterile
16) Chemical Safety	similar							similar

The new device has highly similar indications for use as predicate device: both devices are to make dental plate, bite plates, personal trays, appliances, occlusal splints and night guards. The difference between the indications don't raise different questions of safety and effectiveness.

9. Summary of Biocompatibility

The new device, Flexible Block, is substantially equivalent to the predicate devices that have been on the market for years without any 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 Flexible Block (Model: monolayer; Specification: 98×20mm; Shade: Clear) as the representative in biocompatibility tests and those biocompatibility test reports can be used in the biological evaluation of Flexible Block.

Biocompatibility tests were performed to satisfy the ISO 10993 standards. The test items include Systemic Toxicity; Skin Irritation; Skin Sensitization; In Vitro Cytotoxicity; In Vitro Mammalian Cell TK Gene Mutation Test; In Vitro mammalian chromosome aberration test and Bacterial reverse mutation study.

10. Clinical Performance Data

Not applicable. Clinical performance testing has not been performed for the subject device as it has not been marketed in any area.

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 physical properties are slightly different, but these two devices are in compliance with the relevant standards.

It can be seen that the minor differences between the new device and the predicate device are not of significance and do not raise questions of safety and effectiveness as compared to the predicate device. We conclude that Flexible Block is substantially equivalent to the predicate device described herein.