May 12, 2023

Huliang(shanghai) Bio-Tech Co., Ltd.
℅ Jennifer Liu
Regulatory Affairs Manager
Chenhe Medical Consulting Co., Ltd
Room 113, 7th Floor, Block B, Building 1,
No. A 38, Zhongguancun Street, Haidian District
Beijing, Beijing
China

Re: K223706
Trade/Device Name: Pmma Block
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, EBI, MQC
Dated: February 12, 2023
Received: February 13, 2023

Dear Jennifer Liu:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223706

Device Name
PMMA BLOCK

Indications for Use *(Describe)*
PMMA BLOCK is used for the fabrication removable or temporary dental structures, such as crowns and bridges using milling technology using CAD/CAM.
Indications for Use:
- Temporary anterior and posterior crowns;
- Temporary anterior and posterior bridges;
- Removable structures for dentures;
- Removable structures for therapeutic restorations (night guards, bite splints or occlusal splints).

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.

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K223706

005_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:** May 3, 2023

2. Contact details

2.1 Applicant information:

Name	Huliang(shanghai) Bio-Tech Co., Ltd.
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Tel:	0086- 021-20952966
Contact person and title:	Quansheng Wang, Head of firm
E-mail	walkerwang@leongy.com

2.2 Submission Correspondent

Name	Chenhe Medical Consulting Co., Ltd
Address	Room 113, 7th Floor, Block B, Building 1, No. A 38, Zhongguancun Street, Haidian District, Beijing, China
Tel:	086 633 13774915658
Contact person and title:	Jennifer Liu/Regulatory Affairs Manager
E-mail	Jennifer19862022@163.com

3. Device Name

Trade name: PMMA BLOCK

Common name: Crown And Bridge, Temporary, Resin

Regulatory Class: II

Product Code: **EBG**, EBI, MQC

Classification regulation: 21 CFR 872.3770

Classification Name: Temporary crown and bridge resin

4. Predicate Device Information

Table 1: Predicate Device Information				
Owner/Operator	**Device Trade Name**	**510 (k) No.**	**Product Code**	**Predicate**
HUGE DENTAL MATERIAL CO., LTD.	PMMA BLOCK	K201683	**EBG**, EBI, MQC	Primary

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

No reference devices were used in this submission.

5. Description of Device

PMMA BLOCK is a circular solid (disc) or rectangular solid (block) of PMMA with or without post attachment for use in a CAD/CAM milling machine for production of provisional restorative prostheses such as dental crowns and bridges and removable dental structures. These blocks are available in a variety of shapes for different milling systems and are also available in variety of dental shades.

6. Indications for Use

PMMA BLOCK is used for the fabrication removable or temporary dental structures, such as crowns and bridges using milling technology using CAD/CAM.

Indications for Use:

- Temporary anterior and posterior crowns;
- Temporary anterior and posterior bridges;
- Removable structures for dentures;
- Removable structures for therapeutic restorations (night guards, bite splints or occlusal splints).

7. Summary of Physical and Chemical Properties Tests

- Chemical Composition:

The device has similar chemical composition as the predicate device (Polymethylmetacrilate).

- Technological characteristics:

The device has the same technological characteristics as the predicate device (Hot cured PMMA). And the device is similar in sizes, shapes and color scale as the predicate devices.

- Properties:

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

(Meeting the requirements of ISO standards for the polymer-based dental materials,
ISO 10477, 20795-1, 22112)

- Usage:

The device has similar indications for use as the sum of the predicate devices: making removable or temporary dental structures such as crowns and bridges by CAD/CAM or removable dental structures like denture bases and bite splints.

8. Technological Characteristics

All components of the subject device are based upon industry well-known chemistry. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate device:

Table 4: Device Comparison Table

Comparison Items	**Subject Device**	**Predicate Device**
	PMMA BLOCK	PMMA Block
		K201683
1) Regulatory Classifications	Same	Same
2) Indications for use	Same	Same
3) Contraindications	Same	Same
4) Composition of Materials	PMMA	PMMA

5) Physical Properties	Physical parameters	Flexural strength	Water absorption	Water solubility	Residual monomer content	Dimensional stability
		ISO 10477 ≥ 50 MPa ISO 20795-1 ≥ 65 MPa	ISO 10477 ≤ 0.040 mg/mm^3 ISO 20795-1 ≤ 0.032 mg/mm^3	ISO 10477 ≤ 0.0075 mg/mm^3 ISO 20795-1 ≤ 0.0016 mg/mm^3	ISO 20795-1 ≤ 2.2%	ISO 22112 The dimensional change shall be within±2% of its original mesio-distal dimension.
	Predicate Device (K201683)	≥ 50 MPa ≥ 65 MPa	≤ 0.040 mg/mm^3 ≤ 0.032 mg/mm^3	≤ 0.0075 mg/mm^3 ≤ 0.0016 mg/mm^3	≤ 2.2%	0.29%

Table 4: Device Comparison Table						
Comparison Items	**Subject Device**			**Predicate Device**		
	PMMA BLOCK			PMMA Block K201683		
	Subject device	≥ 50 MPa ≥ 65 MPa	≤ 0.040 mg/mm^3 ≤ 0.032 mg/mm^3	≤ 0.0075 mg/mm^3 ≤ 0.0016 mg/mm^3	≤ 2.2%	0.9%
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 PMMA			Circular solid (disc) or rectangular solid (block) of PMMA		
12) Cautions	similar			similar		
13) Standards Met	same			same		
14) Biocompatibility	ISO 10993-5 Non cytotoxic			ISO 10993-5 Non cytotoxic		
15) Sterility	Non-sterile			Non-sterile		
16) Chemical Safety	similar			similar		

9. Summary of Biocompatibility

The new device, PMMA BLOCK, is substantially equivalent to the predicate devices that have been legally marketed for decades and with no clinical adverse events. The formulation of new 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 The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Implantation.

10. Clinical Performance Data

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

11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the subject device has been shown to be substantially equivalent to the predicate for its intended use. Huliang(shanghai) Bio-Tech Co., Ltd. concludes that the subject device is substantially equivalent to the predicate devices described herein.