November 3, 2020

Huge Dental Material Co., Ltd.
Maggie Zheng
Regulatory Affairs Manager
Middle Shanhai Road
Rizhao City, Shandong Province 276800
China

Re: K201683
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: July 31, 2020
Received: August 5, 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 Srinivas “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)*
K201683

Device Name
PMMA BLOCK

Indications for Use *(Describe)*
PMMA BLOCK particularly suitable for making 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;
- Implant surgical guide;
- 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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# K201683_510 (k) Summary

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:** November 3, 2020

2. **Submitter Information:**


| | |
|---|---|
| Name | HUGE DENTAL MATERIAL CO., LTD. |
| Address | Middle Shanhai Road, 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: PMMA BLOCK

Common name: Dental polymer blanks (discs or blocks)

Classification name: Temporary Crown and Bridge Resin (21 C.F.R. 872.3770)

Regulatory Class: II

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

4. **Substantially Equivalent Device**

Table 1: Predicate Device Information

| | **Company Name** | **Device Name** | **510 (k) NO.** | **Substantially Equivalent (SESE) Decision Date** | **Product code** |
|---|---|---|---|---|---|
| Primary Predicate | Union Dental S.A. | IDODENTINE Dental Polymer Blank | K150432 | 08/14/2015 | **EBG**, EBI, MQC |
| Reference Device | HUGE | PMMA Block | K141421 | 02/09/2015 | EBG |

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

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.

PMMA BLOCK are made with the same material (Hot cured PMMA) that is used for the manufacture of the HUGE Synthetic Polymer Teeth (K101029) and HUGE PMMA Block(K141421). These polymer discs or blocks are especially suited for creating dental structures by means of milling CAD/CAM techniques commonly used in the dental laboratories and in dental practice. The elaboration is designed by a professional, a dental technician or a dentist. This guarantees their correct use, since it is an intermediate product in order to manufacture a custom-made product.

## 6. Indications for use

PMMA BLOCK particularly suitable for making 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;
- Implant surgical guide;
- 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, commonly named as PMMA, the same PMMA that is used for produce HUGE Synthetic Polymer Teeth and HUGE PMMA Block).

- 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:

The new device, PMMA BLOCK, has the same design, materials and chemical composition as the predicate device.

Table 4: Device Comparison Table

| Comparison Items | New Device | Primary Predicate | Reference Device |
|---|---|---|---|
| | PMMA BLOCK | IDODENTINE Dental Polymer Blank | PMMA Block |
| | | K150432 | K141421 |
| 1) Regulatory Classifications | same | same | Not applicable. This reference device only used to confirm the substantial equivalence regarding the raw materials. |
| 2) Indications for use | similar | similar | |
| 3) Contraindications | same | same | |
| 4) Composition of Materials | PMMA | PMMA | PMMA |

| 5) Physical Properties | | Flexural strength | Water absorption | Water solubility | Residual monomer content | Dimensional stability |
|---|---|---|---|---|---|---|
| | Physical parameters | ISO 10477<br>≥ 50 MPa<br><br>ISO 20795-1<br>≥ 65 MPa | ISO 10477<br>≤ 0.040 mg/mm$^3$<br><br>ISO 20795-1<br>≤ 0.032 mg/mm$^3$ | ISO 10477<br>≤ 0.0075 mg/mm$^3$<br><br>ISO 20795-1<br>≤ 0.0016 mg/mm$^3$ | ISO 20795-1<br>≤ 2.2% | ISO 22112<br>The dimensional change shall be within±2% of its original mesio-distal dimension. |
| | Predicate Device (K150432) | 90 MPa | 0.026 mg/mm$^3$ | 0.0000 mg/mm$^3$ | 1.4% | 0.32% |
| | PMMA BLOCK | ≥ 50 MPa<br>≥ 65 MPa | ≤ 0.040 mg/mm$^3$<br>≤ 0.032 mg/mm$^3$ | ≤ 0.0075 mg/mm$^3$<br>≤ 0.0016 mg/mm$^3$ | ≤ 2.2% | 0.29% |
| | **Note:** The reference device is only used to confirm the substantial equivalence regarding the raw materials. | | | | | |

| | | | |
|---|---|---|---|
| 6) Labeling | similar | similar | Not applicable. This reference device only used to confirm the substantial equivalence regarding the raw materials. |
| 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 | |

| Table 4: Device Comparison Table | | | |
|---|---|---|---|
| **Comparison Items** | **New Device** | **Primary Predicate** | **Reference Device** |
| | PMMA BLOCK | IDODENTINE Dental Polymer Blank | PMMA Block |
| | | K150432 | K141421 |
| 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 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 PMMA BLOCK (Model: Multilayer; Specification: 98×20mm; Shade: A4) as the representative in biocompatibility tests and those biocompatibility test reports can be used in the biological evaluation of PMMA BLOCK.

Biocompatibility tests were performed to satisfied the ISO 10993 standards. The test items include Systemic Toxicity; Irritation; Sensitization; 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.

## 11. Summary of Substantial Equivalence

As with the comparison shown in substantial equivalence discussion, these devices are same or similar in almost all aspects. In addition, the new device adds indications for use of night guards compared to the predicate device which falls into the last intended use of removable structures for therapeutic restorations. The details of physical properties are slightly different, but these two devices are in compliance with the ISO 10477, ISO 20795-1 and ISO 22112.

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

## 12. Photo of the device