DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 9, 2015

Rizhao Huge Dental Industry Co., Ltd.
c/o Ms. Helen Nan
General Manager
Wenzhao Cytech Information Service Co., Ltd.
Room 302, No. 21 Building
Kaiyu Garden, Xishan South Road
Wenzhou, Zhejiang 325000
CHINA

Re: K141421
Trade/Device Name: PMMA Block
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: April 15, 2014
Received: December 31, 2014

Dear Ms. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141421

Device Name
PMMA Block

Indications for Use *(Describe)*
PMMA Block is a device made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K141421

Section 5 510(k) Summary

(As required by 21 CFR 807.92(a))

5.1 Submitter Information

· Company: Rizhao Huge Dental Industry Co., Ltd
· Address: No.68 Shanhai Road, Rizhao City, 276800, Shandong Province, China

· Phone: 086-633-2277285

· Fax: 086-633-2277298

· Contact: Steven Song, General Manager

· Date: April 15, 2014.

5.2 Device Information

· Trade/Device Name: PMMA Block

· Classification: Device Class: 2
Review Panel: Dental
Name: Crown And Bridge, Temporary, Resin
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary crown and bridge resin
Product Code: EBG

· Predicate Device: CORPA TEMP PMMA-DISK submitted by WHITE PEAKS DENTAL SYSTEMS GMBH & CO.KG;
K Number: K131664

· Device Description:

This product is a kind of homogeneous high polymer material made from quality polymethylmethacrylate added with cross-linking agents to improve the network structure through a unique polymerization molding technology. It is mainly used for the fabrication of multi-unit, fully or partially anatomical long-term temporary bridge restorations with up to two pontics by CAD/CAM systems. Both anterior and posterior crown & bridge are recommended.

· Intended Use:

PMMA Block is a device made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.

5.3 Comparison of Required Technology Characteristics

Item	Subject Device	Predicate Device
Indication for Use	A device made from PMMA (polymethylmethacrylate) for the fabrication of temporary crowns and bridges and is intended for use in the oral cavity for up to six (6) months while awaiting a permanent restoration. Restorations are designed and manufactured by a dental Professional (Technician) using CAD technology.	Same
Material of Construction	PMMA	Same
Shades	20 Vita Shades	Various Vita Shades
Processing Method	Variable Thickness Milling Blank and machined using any milling system	Same
Flexural Strength	≥50MPA	113MPA
Shelf-life	Five Years	Unknown
Performance Effectiveness	Tested According to ISO 10477	Same
Performance Safety	Tested according to ISO 10993 standards	Same

Brief Summary:

First, the subject device - PMMA Block incorporates the same intended use with the predicate device. Secondly, the subject device shares similar design and fundamental technological characteristics with the predicate device, for example, they are both

composed of PMMA, they enjoy the same processing method. Thirdly, both their safety and effectiveness have been verified by appropriated FDA recognized standards, which ensures that the subject device will be as safe and effective as the predicate device. Last but not least, though the two devices may be different in shelf life, such difference will not affect the core usage of the device, thus will not influence the comparison of substantial equivalence between the two devices.

5.4 Discussion of Tests Performed

· **Clinical Tests:**

Clinical testing has not been conducted on this product.

· **Non-Clinical Tests**

The following standards have been adopted to evaluate the safety and effectiveness of the subject device:

- Biocompatibility Test according to AAMI / ANSI / ISO 10993-3:2003/(R)2009, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity. (Biocompatibility), AAMI / ANSI / ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility), AAMI / ANSI / ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility) and AAMI / ANSI / ISO 10993-11:2006/(R)2010, Biological Evaluation Of Medical Devices – Part 11: Tests For Systemic Toxicity. (Biocompatibility), the detail of which can be found in Attachment D ISO 10993 Test Report of the submission.
- Physical property testing, such as flexural strength, surface polishing performance, bond strength, water sorption, solubility, shade consistency and color stability, according to ISO 10477 Second Edition 2004-10-01, Dentistry - Polymer-Based Crown And Bridge Materials. (Dental/ENT), the test results of which can be found on page 3 of Attachment E ISO 10477 Test Report of the submission. Its results show that the subject device fully meets the requirement, that it will be as effective as the predicate device, which well supports the Substantial Equivalence to the predicate device.

5.5 Conclusion:

First, the subject device - PMMA Block 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.