May 29, 2020

De Corematrix Co.Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, 200120 CHINA

Re: K192262
Trade/Device Name: Dental Zirconia Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 14, 2020
Received: March 2, 2020

Dear Boyle Wang:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192262

Device Name
Dental Zirconia Blocks

Indications for Use *(Describe)*
Dental Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers. All Blocks are processed through dental laboratories or by dental professionals.

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.

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510(k) Summary, K192262

This summary of 510(k) substantial equivalence is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's Information

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Date of Preparation: May.28.2020

Designated Submission Correspondent

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Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Dental Zirconia Blocks
Common name: Powder, Porcelain
Classification name: Porcelain powder for clinical use

3.0 Classification

Production code: EIH
Regulation number: 21 CFR 872.6660
Classification: Class II
Panel: Dental

4.0 Identification of Predicate Device and Reference Device

Primary Predicate Device:

510(k) Number: K182068
Product Name: Erran Dental Zirconia
Manufacturer: Hangzhou Erran Technology Co., Ltd.

Reference Device:

510(k) Number: K141724
Product Name: Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Manufacturer: Liaoning Upcera Company Limited.

5.0 Indication for Use Statement

Dental Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers.
All Blocks are processed through dental laboratories or by dental professionals.

6.0 Device Description

The proposed device, Dental Zirconia Blocks, are derived from zirconia powder，usually using CAD / CAM (computer aided design / computer aided manufacturing) method of making all-ceramic restorations such as crowns,bridges,veneers,inlay, with high strength, hardness, good resistance to fracture toughness and wear resistance.

They are available in different models that differ in various specification and color. Two main models for Dental Zirconia Block are CMW series and CMC series in which CMW series represents the White Zirconia(W1,W2 and W3) and the CMC series represents the Color Zirconia (A1,A2,A3,A3.5,A4,B1,B2, B3,B4,C1,C2,C3,C4,D1,D2,D3,D4,T1,T2 and T3).

The white zirconia is composed of ZrO_2+HfO_2+Y_2O_3 and an additional inorganic pigment: Al_2O_3 and Other oxide. The colour zirconia are derived from the same zirconia powder as the regular white zirconia powder, with the addition of very small amount of inorganic pigments: Fe_2O_3 +Pr_2O_3 +Er_2O_3. The inorganic pigments generate the color on the prosthetic dental device, after sintering at dental labs, that matches natural color of patient's teeth.

The composition of the Dental Zirconia Blocks including the white zirconia and the colour zirconia conforms to ISO 13356:2015, Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) and the performance conforms to ISO 6872:2015/Amd1:2018, Dentistry: Ceramic Materials.

The Dental Zirconia Blocks are provided as non-sterile.

7.0 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 6872:2015/Amd1:2018 Dentistry - Ceramic Materials
ISO 10993-3: 2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-6 Biological evaluation of the medical devices – Part 6: Tests for Local Effects after Implantation.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2017 Biological evaluation of medical device – Part 11: Tests for systemic toxicity

8.0 Clinical Test Conclusion

Clinical testing was not required for this submission.

9.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 6-1 General Device Characteristics Comparison Table

Item	**Proposed device K192262**	**Primary Predicate device K182068**	**Reference device K141724**	**Remark**
Product Name	Dental Zirconia Blocks	Erran Dental Zirconia	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	--
Product Code	EIH	EIH	EIH	Same
Regulation No.	872.6660	872.6660	872.6660	Same
Class	II	II	II	Same
Intended Use	Dental Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers. All Blocks are processed through dental laboratories or by dental professionals.	Erran Dental Zirconia Blocks are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers. All Blocks are processed thought dental laboratories or by dental professionals.	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines.All blanks are processed thought dental laboratories or by dental professionals.	Same with the Predicate Device
Prescription Use	Yes	Yes	Yes	Same
Shapes	Blocks, disc	Blocks, powder	Blocks, disc, and rod.	Same
Color	White and Colour	None	None,and pre-shaded	Analysis 1

<table>
<tr>
<td>Chemical Composition (Weight %)</td>
<td>White zirconia:
<table>
<tr><td>$ZrO_2+HfO_2+Y_2O_3$</td><td>≥99.0</td></tr>
<tr><td>Y_2O_3</td><td>4.5 ～ 6.0</td></tr>
<tr><td>HfO_2</td><td>≤5</td></tr>
<tr><td>Al_2O_3</td><td>≤0.5</td></tr>
<tr><td>Other oxide</td><td>≤0.5</td></tr>
</table>
Colour zirconia:
<table>
<tr><td>$ZrO_2+HfO_2+Y_2O_3$</td><td>≥98.0</td></tr>
<tr><td>Fe_2O_3</td><td><0.3</td></tr>
<tr><td>Pr_2O_3</td><td><0.2</td></tr>
<tr><td>Er_2O_3</td><td><1</td></tr>
<tr><td>Other oxide</td><td>≤0.5</td></tr>
</table></td>
<td>Zirconia($ZrO_2+HfO_2+Y_2O_3$ ≥99.0)</td>
<td>Regular:
Zirconia($ZrO_2+HfO_2+Y_2O_3+Al_2O_3$≥99.0);
Pre-Shaded:
Zirconia($ZrO_2+HfO_2+Y_2O_3+Al_2O_3$≥98.0)
Inorganic pigments: $Fe_2O_3+Pr_2O_3+Er_2O_3$ <2.0</td>
<td>Analysis 1</td>
</tr>
<tr><td>Dimension</td><td>Various</td><td>Various</td><td>Various</td><td>Same</td></tr>
<tr><td>Density (pre sintering)</td><td>≥ 3.0 g / cm^3</td><td>3.10g/cm^3</td><td>2.8~3.2 g/cm^3</td><td>Analysis 2</td></tr>
<tr><td>Density (post sintering)</td><td>≥ 6.02 g / cm^3</td><td>≥ 6.02 g / cm^3</td><td>≥ 6.02 g / cm^3</td><td>Same</td></tr>
<tr><td>Sintering Temperature</td><td>1400-1600 ℃</td><td>1350-1600℃</td><td>>1500℃</td><td>Analysis 3</td></tr>
<tr><td>Flexural strength</td><td>> 800MPa</td><td>> 800MPa</td><td>≥900 MPa</td><td>Same with the Predicate Device</td></tr>
<tr><td>Solubility</td><td><100 μg.cm^{-2}</td><td><100μg/ cm^2</td><td><100μg/ cm^2</td><td>Same</td></tr>
</table>

Radioactive	uranium-238 active concentration ≤ 1.0 Bq / g.	The activity concentration of U-238is not more than 1.0 Bq / g.	Unknown	Same with the Predicate Device
Single Use	Yes	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Performance Test	Including: Appearance Test, Dimension Test, Density Test, Product composition Flexural strength, Linear thermal expansion-coefficient Chemical solubility Radioactivity of dental ceramic, Fracture toughness which comply with ISO 6872	Comply with ISO 6872	Comply with ISO 6872	Same
Biocompatibility	Comply with ISO 10993-1:2018, FDA Guidance, tests included cytotoxicity, oral mucosa irritation, skin sensitization,	Comply with ISO 10993-1, FDA Guidance	Comply with ISO 10993-1, FDA Guidance	Same

	pyrogenicity, acute systemic toxicity, subacute toxicity, subchronic systemic toxicity, implantation effect and genotoxicity etc.			
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same

Analysis:

The proposed device is highly similar to the predicate device in terms of indications for use, design, material and processing.

The proposed device is different from the predicate device in the following:

1) The proposed device has white and colour zirconia blocks. The chemical compositions of white zirconia are same with that of predicate device. The chemical compositions of color zirconia are same with the that of reference device's pre-shaded zirconia blanks. The color is originated from inorganic pigments Fe_2O_3,Pr_2O_3 and Er_2O_3, that are of very small amount(<2.0%). All chemical ingredients in the proposed device have been used in the predicate device and the reference device. Accordingly, it was concluded that the proposed device is substantially equivalent in biocompatibility to the predicate device and the reference device.
2) The pre sintering mainly affects the hardness of products which reflects the easy degree of material machining operations. The pre sintering density of the proposed device is a little different with the predicated device and the reference device, but it has no obvious effect on the hardness, this difference does not affect substantial equivalence.
3) The sintering temperature is about 1350-1600℃ for the predicated device, while this information is a little different with the proposed device which is about 1400-1600℃. This difference does not affect substantial equivalence as the sintering temperature mainly affects the physical and mechanical property of the dental blocks. Both the proposed and predicate device have similar physical/mechanical properties that met the requirements of ISO 6872.

In summary, the main components of the proposed device and its predicate are substantially equivalent, and the slight differences does not affect the substantial equivalence of the proposed device when compared to the predicate device.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the proposed device and the predicated device are insignificant in terms of substantial equivalence. The proposed device is is substantially equivalent to the predicate device.