



Hangzhou Erran Technology Co., Ltd.  
Tingkai Li  
Chief Technology Officer  
Room F3022, Floor 3, Building 1 (south) No. 368 Liuhe Road  
Hangzhou, 310053 Cn

December 13, 2018

Re: K182068  
Trade/Device Name: Erran Dental Zirconia  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder For Clinical Use  
Regulatory Class: Class II  
Product Code: EIH  
Dated: July 28, 2018  
Received: August 1, 2018

Dear Tingkai Li:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner Digitally signed by Mary S.  
Runner-S3  
Date: 2018.12.13 15:28:20  
-05'00'

-S3

For

Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K182068

Device Name

Erran Dental Zirconia

Indications for Use (Describe)

Erran Dental Zirconia are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers.

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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Hangzhou Erran Technology Co.,Ltd

## **510(k) Summary      K182068**

### **1. Date**

August 28, 2018

### **2. Submitter**

Hangzhou Erran Technology Co.,Ltd.  
Room F3022, Floor 3, Building 1 (south)No. 368 Liuhe Road, Binjiang District  
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### **3. Official contact person**

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### **4. Product information**

**Proprietary Name**  
Erran Dental Zirconia

**Common Name**  
Dental Zirconia Ceramics

**Classification Name (Number)**  
Porcelain powder for clinical use (872.6660)



Hangzhou Erran Technology Co.,Ltd

**Proposed Regulatory Class**

Class II

**Product Code**

EIH

**Predicate Devices**

Aidite Zirconia Dental Ceramics (K111291)

## 5. Device Description

Normally, Erran Dental Zirconia are offered in blocks and powder and the size as shown below in Table 5-1, and are similar to the sizes and shapes of the predicate device.

There are two types of our device, one is block, another is powder. The main difference is that the blocks are made by powder, zirconia blocks is prepared and have a fixed shape, while zirconia powder is used to directly product the shape of the tooth.

Erran Dental Zirconia are derived from Zirconia powder that has been processed into their final net shapes. Erran Dental Zirconia have are then being further fabricated in to all-ceramic restoration such as crowns, bridge, veneers, inlay/onlay. The zirconia powder is composed of  $ZrO_2+Y_2O_3+HfO_2+Al_2O_3$  with its composition conforms to ISO13356-2015, Implants for Surgery-Ceramic Materials Based in Yttria-Stabilized Tetragonal Zirconia(Y-TZP). The performance of the dental zirconia conforms to ISO 6872-2015, Dentistry: Ceramic Materials.

**Table 5-1 The normal model of Erran Dental Zirconia**

|                    | Model (Device size, unit: mm)                                       |
|--------------------|---------------------------------------------------------------------|
| Cuboid blocks      | (Length - width - height, unit: mm) 20-14-15; 20-19-15;<br>40-14-15 |
| Cylindrical blocks | (Diameter - Thickness, unit: mm) D15-16; D18-14; D98-14             |
| Powder             | (Weight, unit: g) 60                                                |

## 6. Indications for Use

Erran Dental Zirconia are intended for use for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers.



## 7. Summary of Device Testing

Bench testing was performed per ISO 6872-2015 and internal procedures to ensure that the Erran Dental Zirconia met its specification. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

The following table 5-2 shows test requirement and result of our device. Tests were conducted following the recommended procedures outline in the FDA recognized consensus standard of ISO 6872-2015, ISO7405-2008 and ISO 10993-1-2009, and results meet all relevant requirements in the test standards.

**Table 5-2 Test summary table**

| Item                                   | The Requirements                                                                     | Result                                                                              |         | Conclusion              |
|----------------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------|-------------------------|
| Chemical Composition(%)                | Meet the ISO 13356-2015                                                              | ZrO <sub>2</sub> +HfO <sub>2</sub> +Y <sub>2</sub> O <sub>3</sub>                   | ≥99     | Meet the ISO 13356-2015 |
|                                        |                                                                                      | Y <sub>2</sub> O <sub>3</sub>                                                       | 4.5~6.6 |                         |
|                                        |                                                                                      | HfO <sub>2</sub>                                                                    | ≤5      |                         |
|                                        |                                                                                      | Al <sub>2</sub> O <sub>3</sub>                                                      | ≤0.5    |                         |
|                                        |                                                                                      | SiO <sub>2</sub>                                                                    | ≤ 0.3   |                         |
|                                        |                                                                                      | Fe <sub>2</sub> O <sub>3</sub>                                                      | ≤ 0.2   |                         |
| Appearance                             | There is no spot cracks and foreign matter on the surface of Erran Dental Zirconia.  | There is no spot cracks and foreign matter on the surface of Erran Dental Zirconia. |         | Conform                 |
| Size(mm)                               | The size deviation of zirconia blocks is within 1.0mm.                               | Meet the requirement.                                                               |         | Conform                 |
|                                        | The weight deviation of zirconia powder is within 10g.                               |                                                                                     |         |                         |
| Density (g/cm <sup>3</sup> )           | Not less than 2.6, the deviation is less than 0.05 compared with marked value(3.16). | Meet the requirement.                                                               |         | Conform                 |
| Sintering density (g/cm <sup>3</sup> ) | Not less than 6.02                                                                   | 6.025                                                                               |         | Conform                 |



|                                                                 |                                                                                                                                                 |                                                                                                                                                                                                                                        |         |
|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| Fracture Toughness (post sintering) (MPa)                       | At least 8 samples of the 10 samples have a fracture toughness greater than 800                                                                 | The samples met the criteria。                                                                                                                                                                                                          | Conform |
| Chemical solubility ( $\mu\text{g}/\text{cm}^2$ )               | < 100                                                                                                                                           | 12.42                                                                                                                                                                                                                                  | Conform |
| Shrinkage                                                       | At least 8 samples of the 10 samples have a Shrinkage which should between 19~27                                                                | Average is 19.61, all samples are between 19 - 27 range.                                                                                                                                                                               | Conform |
| Mixing and condensation properties(only for zirconia powder)    | After the zirconia powder is compacted, it should not be cracked or broken, and after forming compaction, it may not be agglomerated.           | The samples meet the requirements。                                                                                                                                                                                                     | Conform |
| The coefficient of thermal expansion (only for zirconia powder) | $6.5 \times 10^{-6} \text{ K}^{-1} \sim 11.5 \times 10^{-6} \text{ K}^{-1}$ , the deviation is less than $0.5 \times 10^{-6} \text{ K}^{-1}$    | $10.5 \times 10^{-6} \text{ K}^{-1}$                                                                                                                                                                                                   | Conform |
| Radioactivity                                                   | The activity concentration of U-238 is not more than 1.0                                                                                        | <0.005                                                                                                                                                                                                                                 | Conform |
| Cytotoxicity                                                    | Biocompatibility testing including cytotoxicity, mucosal irritation, sensitization conducted in accordance with ISO 7405-2008 and ISO 10993-10. | We conducted comparative performance testing for biocompatibility testing including cytotoxicity, mucosal irritation, sensitization and etc. conducted in accordance with ISO 7405-2008 and ISO 10993-10, and meet the requirements。 . | Conform |
| Irritation Oral Mucosa Irritation                               |                                                                                                                                                 |                                                                                                                                                                                                                                        |         |
| Sensitization                                                   |                                                                                                                                                 |                                                                                                                                                                                                                                        |         |
| Subacute Subchronic Toxicity                                    |                                                                                                                                                 |                                                                                                                                                                                                                                        |         |
| Genotoxicity                                                    |                                                                                                                                                 |                                                                                                                                                                                                                                        |         |



## 8. Comparison to Predicate Device

The following table 5-3 shows similarities and differences of use, design, and the materials between our device and the predicate devices.

**Table 5-3 Comparison to Predicate Device(Zirconia Dental Ceramic)**

| Description              | Erran Dental Zirconia K182068                                                                                                                                                                                                                 | Predicate Device K111291                                                                                                                                                                                                                         | Comparison                                        |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| Indication for use       | 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. | Aidite Zirconia Dental Ceramics are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers. All Blanks are processed thought dental laboratories or by dental professionals. | Same                                              |
| Single Use               | Yes                                                                                                                                                                                                                                           | Yes                                                                                                                                                                                                                                              | Same                                              |
| Color                    | None                                                                                                                                                                                                                                          | None, and Pre-shaded (for Pre-shaded series)                                                                                                                                                                                                     | Different, Does not affect the use of the product |
| Type Specification       | Blocks, powder                                                                                                                                                                                                                                | Blocks, disc, and rod                                                                                                                                                                                                                            | Different, Does not affect the use of the product |
| Materials                | Zirconia( $ZrO_2+Y_2O_3+HfO_2 \geq 99.0\%$ )                                                                                                                                                                                                  | Zirconia( $ZrO_2+Y_2O_3+HfO_2 +Al_2O_3 \geq 99.0\%$ )                                                                                                                                                                                            | Different, Does not affect the use of the product |
| Crystal Morphology       | Tetragonal                                                                                                                                                                                                                                    | Tetragonal                                                                                                                                                                                                                                       | Same                                              |
| Porosity                 | 0%                                                                                                                                                                                                                                            | 0%                                                                                                                                                                                                                                               | Same                                              |
| Sintering temperature    | 1350-1600°C                                                                                                                                                                                                                                   | 1480°C                                                                                                                                                                                                                                           | Different                                         |
| Density (pre sintering)  | 3.10g/cm <sup>3</sup>                                                                                                                                                                                                                         | 3.10g/cm <sup>3</sup>                                                                                                                                                                                                                            | Same                                              |
| Density (post sintering) | >6.02g/cm <sup>3</sup>                                                                                                                                                                                                                        | 6.05g/cm <sup>3</sup>                                                                                                                                                                                                                            | Different, Does not affect the use of the         |



|                                    |                                                                                                                                                                                                                                      |                                                          |                                                   |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------|
|                                    |                                                                                                                                                                                                                                      |                                                          | product                                           |
| Fracture Toughness (pre sintering) | 55Mpa                                                                                                                                                                                                                                | 55Mpa                                                    | Same                                              |
| Bending strength                   | > 800MPa;                                                                                                                                                                                                                            | > 800MPa;                                                | Same                                              |
| Shrinkage                          | 19%-27%                                                                                                                                                                                                                              | 22.00%                                                   | Different, Does not affect the use of the product |
| Elastic modulus (post sintering)   | 210Gpa                                                                                                                                                                                                                               | 210Gpa                                                   | Same                                              |
| Porosity                           | 0%                                                                                                                                                                                                                                   | 0%                                                       | Same                                              |
| Chemical solubility                | <100µg/cm <sup>2</sup>                                                                                                                                                                                                               | <100µg/cm <sup>2</sup>                                   | Same                                              |
| Radioactive                        | The activity concentration of U-238is not more than 1.0.                                                                                                                                                                             | The activity concentration of U-238is not more than 1.0. | Same                                              |
| Cytotoxicity                       | We conducted comparative performance testing for biocompatibility testing including cytotoxicity, mucosal irritation, sensitization and etc. conducted in accordance with ISO 7405-2008 and ISO 10993-10, and meet the requirements. | No biocompatibility testing provided in the submission   | Different                                         |
| Irritation Oral Mucosa Irritation  |                                                                                                                                                                                                                                      |                                                          |                                                   |
| Sensitization                      |                                                                                                                                                                                                                                      |                                                          |                                                   |
| Subacute Subchronic Toxicity       |                                                                                                                                                                                                                                      |                                                          |                                                   |
| Genotoxicity                       |                                                                                                                                                                                                                                      |                                                          |                                                   |

Erran Dental Zirconia meets the requirement per ISO6872-2015 and ISO7405-2015. Its performance meets the requirements of its predefined acceptance criteria and intended use, and results are also comparable to the predicate device as evidenced in comparative performance testing.

## 9. Substantial Equivalence Conclusion

Bases upon technology, indications for use, and non-clinical performance testing, Erran Dental Zirconia Blocks is substantially equivalent to Aidite Zirconia Dental Ceramics K111291.