DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 29, 2016

Shenzhen XiangTong Photoelectricity Technology Co., Ltd.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K153767
Trade/Device Name: X-cera Zirconia Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: March 9, 2016
Received: March 15, 2016

Dear Mr. Job:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 below.

510(k) Number *(if known)*
K153767

Device Name
X-cera Zirconia Blanks

Indications for Use *(Describe)*

X-cera Zirconia Blanks are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, 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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510(k) Summary

for

X-cera Zirconia Blanks

1. **510(k) Number**
   K153767

2. **Submission Sponsor**

   Shenzhen XiangTong Photoelectricity Technology Co., Ltd.
   2~4th floor, 1st Building, South Industrial park of Honghualing,
   Nanshan District, Shenzhen, China
   Phone: 0086-755-86001804
   Fax: 0086-755-86001486
   Contact: Yongqing Chen, Vice-President

3. **Submission Correspondent**

   Emergo Group
   816 Congress Avenue, Suite 1400
   Austin, TX 78701
   Cell Phone: +86-21-22815850
   Office Phone: (512) 327.9997
   Fax: (512) 327.9998
   Contact: Lee Fu, RAC, Senior Consultant, Regulatory
   Email: project.management@emergogroup.com

4. **Date Prepared**

   03/29/2016

5. **Device Identification**

Trade/Proprietary Name:	X-cera Zirconia Blanks
Common/Usual Name:	Zirconia Blocks
Classification Name:	Porcelain powder for clinical use
Classification Regulation:	872.6660
Product Code:	EIH
Device Class:	Class II
Classification Panel:	Dental Devices

6. **Legally Marketed Predicate Device(s)**

   Aidite Zirconia Dental Ceramics (K111291)

7. Device Description

X-cera Zirconia Blanks are provided in either block, disc, cylinder shape and are derived from zirconia powder that has been processed via uni-axial die pressing, followed by iso-static pressing, to achieve final net shapes of uniform density and distribution. These Zirconia Blanks can be fabricated into various prosthetic dental device.
X-cera Zirconia Blanks are offered in ten(10) different product families of shapes and a multitude of different sizes as shown in Figure 1 and Table 1 and are capable of being machined into complex dental shapes using modern machining methods and are similar to the sizes and shapes of the predicate device.

Any difference in the net shapes and dimensions between X-cera Zirconia Blanks and those offered by the manufacturer of the predicate devices are incidental to the performance of the final dental prosthetic devices that will be fabricated from them.

Figure 1 X-cera Zirconia Blanks

Table 2 X-cera Zirconia Blanks Product Family(Model)	
Family(Model)	Shapes & Sizes available
XQ series	Cylinder：Φ22*25(mm) Disc: Φ98×8(mm) Discs: Φ100×10 to Φ100×25(mm) (with 3mm protruding step)
XW series	Discs: Φ98×10 to 98×25(mm) (with 2mm protruding step)
XO series	Discs: Φ100×10 to Φ100×25(mm) (with Φ112×6mm Outer plastic ring)
XA series	Discs: Φ98×10 toΦ98×25(mm) (with Ø 115×10mm Outer ring) Discs: Φ71×10 toΦ71×25(mm) Blocks: 40×20×16 to 65×30×20(mm) Blocks: 90×72×10 to 90×72×25(mm)(outer ring)
XK series	Discs: Φ98×10 to Φ98×25(mm) Blocks: 42×16×16 to 60×25×20(mm) Cylinders: Φ16×16 to Φ20×20(mm)
XZ series	Discs: Φ95×10 to Φ95×25(mm) Blocks: 43×25×16 to 93×75×25(mm)

	Cylinders: Φ23×16 to Φ23×22(mm)
XM series	Blocks: 43×25×16 to 75×42×22(mm)
XC series	CylindersΦ25×26 toΦ25×60(mm) (with Outer plastic ring) Blocks: 26×25×20 to 72×40×25(mm) (with Outer plastic ring)
XS series	Blocks: 20×14×15 to 85×40×22(mm)
XZZ series	Discs: Φ95×10 to Φ95×25(mm)

Note: The form of size above has two forms, one is shown in D×H and the other is L×W×H, of which, "D" means Diameter, "H" means height, "L" means length, "W" means width.

8. Indication for Use Statement

X-cera Zirconia Blanks are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

9. Substantial Equivalence Discussion

The following table compares the X-cera Zirconia Blanks to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 3 – Comparison of Characteristics

Manufacturer	**Shenzhen XiangTong Photoelectricity Technology Co., ltd.**	**Qinhuangdao Aidite High-Technical Ceramics Co.**	**SIGNIFICANT DIFFERENCES**
Trade Name	X-cera Zirconia Blanks	Aidite Zirconia Dental Ceramics	/
510(k) Number	/	K111291	/
Product Code	EIH	EIH	Same
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	Same
Regulation Name	Powder, Porcelain	Powder, Porcelain	Same
Indications for Use	are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers	are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers	Same
Directions for Use	Prescription Use	Prescription Use	Same
Fundamental Scientific Technology	Iso static pressing	Iso static pressing	Same
Main working principle	Be capable of being machined into complex dental shapes using modern machining	Be capable of being machined into complex dental shapes using modern machining	Same

Manufacturer	**Shenzhen XiangTong Photoelectricity Technology Co., ltd.**	**Qinhuangdao Aidite High-Technical Ceramics Co.**	**SIGNIFICANT DIFFERENCES**
Trade Name	X-cera Zirconia Blanks	Aidite Zirconia Dental Ceramics	/
	methods	methods	
Applied Standards	ISO 6872 ISO 10993-1 ISO 7405	ISO 6872 ISO 10993-1 ISO 7405	Same
Main Chemical Composition (in mass-%)	ZrO_2 88% ~ 96% Y_2O_3 4% ~10% Al_2O_3＜1% HfO_2＜0.05% SiO_2＜0.5%	ZrO_2 ＜96% Y_2O_3＞4% Al_2O_3＜1% HfO_2＞1% SiO_2＜0.02%	Analysis 1
Crystal Morphology	Tetragonal	Tetragonal	Same
Color	white	white	Same
Sintering temperature	1480℃	1480℃	Same
Sterile	Non-sterile	Non-sterile	Same
Density (post sintering)	6.0~6.1 g/cm^3	6.05g/cm^3	Analysis 2
Shrinkage (post sintering)	19%~22%	22%	Analysis 3
Categorization According to ISO 7405 and ISO 10993-1	1) Categorization by nature of contact: External communicating devices 2) Categorization by duration of contact Permanent contact devices	1) Categorization by nature of contact: Surface-contacting devices 2) Categorization by duration of contact Permanent contact devices	Same
Flexural Strength (post sintering)	Comply with ISO 6872	Comply with ISO 6872	Same
Elastic modulus (post sintering)	210±15 GPa	210 GPa	Same
Porosity	Less than 0.1%	0%	Same
Type and Class according to ISO 6872	Type II Class 6	Type II Class 6	Same
Fracture Toughness (after sintered)	Comply with ISO 6872	Comply with ISO 6872	Same
Coefficient of linear thermal expansion	10.5±0.5×10^{-6} K^{-1}(25℃~500℃)	10.5±0.5×10^{-6} K^{-1}(25℃~500℃)	Same

Analysis 1
They are both conformance with the requirement ISO 6872 Type II class 6.

Analysis 2
The value of Density (post sintering) of Aidite Zirconia Dental Ceramics is a fixed value, and the range of the proposed cover the value of the predicate.

Analysis 3
Proposed device and predicate device are both conformance to the same mechanical and chemical property and biocompatibility standard (ISO 6872, ISO 10993-1, ISO 7405).

10. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

- Flexural Strength Test - The test results of mean flexural strength (post sintering) comply with the ISO 6872: 2008 (≥800MPa) and product design requirement (≥900MPa).
- Density and Apparent Porosity Test - The test results of density and apparent porosity comply with the values specified by manufacturer in the Instruction for Use.
- Shrinkage rate and Expand Rate Test - The test results of shrinkage rate and expand rate comply with the acceptance criteria.
- Physical and chemical test - The test results comply with the ISO 6872: 2008.
- Zirconia powder Composition Test - The test results comply with the design specifications and the values specified by manufacturer in the Instruction for Use.
- Biocompatibility Test – Results comply with ISO 7405 and ISO 10993 including In Vitro Cytotoxicity Test, Sensitization Test, Intracutaneous Reactivity Test, Acute Systemic Test, and Genotoxicity.

The X-cera Zirconia Blanks passed all testing stated above as shown by the acceptable results obtained.

The device passed all the testing in accordance with national and international standards.

11. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device.

12. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The X-cera Zirconia Blanks, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.