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

December 4, 2015

Liaoning Upcera Co., Ltd.
c/o Mr. Charles Shen
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K152175
Trade/Device Name: Dental Zirconia Blank for Aesthetic Restoration
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 1, 2015
Received: November 3, 2015

Dear Mr. Shen:

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" (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 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)*
K152175

Device Name
Dental Zirconia Blank for Aesthetic Restoration

Indications for Use *(Describe)*

"Dental Zirconia Blank for Aesthetic Restoration" is mainly used in prosthetic treatment. When the flexural strength of Dental Zirconia Blank for Aesthetic Restoration after sintering is between 300-500 MPa, the product can be used for veneering, inlay, single crown, and substructure ceramic for three-unit prostheses not involving molar restoration; when the flexural strength of Dental Zirconia Blank for Aesthetic Restoration after sintering is over 500 MPa, it can be used for veneering, inlay, single crown, and substrate ceramic for three-unit prostheses. All blanks 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K152175

510(k) Summary:

Submitter & Foreign Manufacture Identification

Liaoning Upcera Co., Ltd
No.122 Xianghuai Road, Economic Development Zone, Benxi, Liaoning, China
Tel： (086)-24-45565006
Submitter's FDA Registration Number：3010582952
www.upcera-dental.com

Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: December 1, 2015

Device Name:	
Proprietary Name:	Dental Zirconia Blank for Aesthetic Restoration
Common Name:	Dental Zirconia Ceramics
Classification Name:	Powder, Porcelain
Device Classification:	II
Regulation Number:	21 CFR 872.6660
Panel: General	Dental
Product Code:	EIH

Predicate Device Information:

- K093560, "Upcera Zirconia Blanks", manufactured by "Shenyang Upcera Co., Ltd."

Device Description:

"Dental Zirconia Blank for Aesthetic Restoration" is derived from zirconia powder that has been processed through various molding and sintering techniques – into their final net shapes. These blanks are then further fabricated into various prosthetic dental devices intended for use in the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers. The zirconia powder is composed of ZrO_2 + Y_2O_3 +

HfO_{2+} Fe_2O_3+ Er_2O_3+ Al_2O_3. The performance of formed zirconia dental blanks conforms to *ISO 6872, Dentistry, Ceramic Materials.*

"Dental Zirconia Blank for Aesthetic Restoration" is ceramic dental blanks designed for the manufacture of ceramic dental prosthetic devices. The dental prosthetic devices are fabricated by CAD/CAM machining processes. All prosthetic dental devices are intended for single use applications. At the dental lab, the blanks are held to the CAD/CAM machine which is used to machine to the final dental restoration. At the completion of the machining steps, the dental restoration is fired (i.e., sintered) in the oven to harden the ZrO_2 so that its final properties can be achieved.

"Dental Zirconia Blank for Aesthetic Restoration" is supplied in different shapes, such as blocks, discs, rods, or customer ordered shapes. It is also supplied in the combinations of forty-six different colors, three different translucencies, and two different aesthetic effects (single and multilayer).

The different colors are originated from the different constituent of color additives (such as Fe_2O_3, Er_2O_3); the different translucencies are originated from small difference in the amount of Y_2 O_3, and the different aesthetic effects are originated from the different padding method used in the process of dry pressing.

Intended Use:

"Dental Zirconia Blank for Aesthetic Restoration" is mainly used in prosthetic treatment. When the flexural strength of Dental Zirconia Blank for Aesthetic Restoration after sintering is between 300-500 MPa, the product can be used for veneering, inlay, single crown, and substructure ceramic for three-unit prostheses not involving molar restoration; when the flexural strength of Dental Zirconia Blank for Aesthetic Restoration after sintering is over 500 MPa, it can be used for veneering, inlay, single crown, and substrate ceramic for three-unit prostheses. All blanks are processed through dental laboratories or by dental professionals.

Summary of Device Testing:

Bench testing was performed per ISO 6872:2008 and internal procedures to ensure that the "Dental Zirconia Blank for Aesthetic Restoration" met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalence of the materials that are used.

Technological Comparison with Predicate Device

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

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Subject Device (K152175)	Predicate Device (K093560)
Indications for Use	"Dental Zirconia Blank for Aesthetic Restoration" is mainly used in prosthetic treatment. When the flexural strength of Dental Zirconia Blank for Aesthetic Restoration after sintering is between 300-500 MPa, the product can be used for veneering, inlay, single crown, and substructure ceramic for three-unit prostheses not involving molar restoration; when the flexural strength of Dental Zirconia Blank for Aesthetic Restoration after sintering is over 500 MPa, it can be used for veneering, inlay, single crown, and substrate ceramic for three-unit prostheses. All blanks are processed through dental laboratories or by dental professionals.	Upcera Zirconia Blanks are indicated for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.
Basic Design	Blocks, disc, and rod	Blocks, disc, and rod
Materials	Zirconia (ZrO_2 + Y2 O3 + HfO_2 + $Al_2O_3 \geq$ 98%) Inorganic pigments	Zirconia (ZrO_2 + Y_2O_3 + HfO_2 + $Al_2O_3 \geq 99.0\%$)
Processing	Sintering at temperature > 1400 °C	Sintering at temperature > 1500 °C
Dimension	Various	Various
Single Use	Yes	Yes
Color	Forty six colors, three translucencies, and two different aesthetic effects (single and multilayer)	None
Sterile	Non-sterile	Non-sterile

Our device is equivalent to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. Slight differences are also noted between the subject and predicate devices. First, the subject device and predicate device have different Indications for Use language. The subject device is specific regarding the application based on the flexural strength; however, both devices are equivalent, in terms of intended use. Both devices are intended to be used for dental restorations using CAD/CAM or manual milling machines, and are to be processed by dental professionals.

The most important difference noted between the subject and predicate devices relates to physical properties. The predicate device has no color, while our proposed device has both the white regular one and pre-shaded series of forty six different colors, three different translucencies, and two different aesthetic effects (single and multilayer).

The different colors are originated from the different constituent of color additive (such as Fe2O3,

Er2O3); the different translucencies are originated from small difference in the amount of Y2 O3, and the different aesthetic effects are originated from the different padding method used in the process of dry pressing. These differences do not raise any concerns in the subject device, and this is demonstrated by biocompatibility testing.

Comparison of Performance with Predicate Device

Performance testing was performed on the subject device and results were compared with predicate device. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 6872, and results met all relevant requirements in the test standard. Test results on radioactivity, pre-sintered density, sintered density, and flexural strength of the subject device are very similar to the predicate device.

The following table shows similarities and differences of the biocompatibility between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the FDA recognized consensus standard of ISO 10993. Results met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Biocompatibility Testing

Description	Subject Device	Predicate Device (K093560)
Cytotoxicity (ISO 10993-5:2009)	No cytotoxicity effect	No cytotoxicity effect
Irritation Oral Mucosa Irritation (ISO 10993-10: 2010)	Not a primary oral mucosa irritant under the conditions of the study	No intracutaneous reactivity
Sensitization (ISO 10993-10: 2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study
Subacute and Subchronic Toxicity (ISO 10993-11: 2006)	No subchronic toxic effects observed	No subchronic toxic effects observed
Genotoxicity (ISO 10993-3: 2003)	No genotoxic effects observed	N/A

Therefore, "Dental Zirconia Blank for Aesthetic Restoration" manufactured by "Liaoning Upcera Co., Ltd." meet requirements per ISO 6872 and ISO 10993-1. Its performance meets the requirements of its pre-defined acceptance criteria and intended uses. The test results are also comparable to the predicate device.

Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "Dental Zirconia Blank for Aesthetic Restoration" and its predicate device have equivalent indications for use, similar material

composition and biocompatibility, similar manufacturing process, and similar performance.

The differences between the “Dental Zirconia Blank for Aesthetic Restoration” and their predicate device do not raise any question regarding its equivalence.

“Dental Zirconia Blank for Aesthetic Restoration”, as designed and manufactured, is equivalent to its predicate device, and therefore is substantially equivalent to its predicate device.