December 10, 2020

Dongguan Xiangtong Co., Ltd.
% Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K202673
Trade/Device Name: X-cera Pre-shaded Zirconia Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 15, 2020
Received: September 15, 2020

Dear Charles 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. 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 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)*
K202673

Device Name
X-cera Pre-shaded Zirconia Blanks

Indications for Use *(Describe)*
X-cera Pre-shaded Zirconia Blanks are Intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist. 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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Section 5: 510(k) Summary: K202673

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

DONGGUAN XIANGTONG CO., LTD
NO.4, Tech 9th Rd, Hi-Tech Industrial Development Zone, Songshan Lake,
Dongguan,Guangdong, China., Zipcode 523808
Tel：(086)-0755-22895688
Submitter's FDA Registration Number：N/A

5.2 Contact Person

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

5.3 Date of Summary: August 29, 2020

5.4 Device Name:

Proprietary Name:	X-cera Pre-shaded Zirconia Blanks
Common Name:	Dental Zirconia Ceramics
Classification Name:	Powder, Porcelain
Device Classification:	II
Regulation Number:	21 CFR 872.6660
Panel: General	Dental
Product Code:	EIH

5.5 Primary Predicate Information:

(1) K093560, "Upcera Zirconia Blanks", manufactured by "Shenyang Upcera Co., Ltd."

5.6 Device Description:

"X-cera Pre-shaded Zirconia Blanks" 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.*

"X-cera Pre-shaded Zirconia Blanks" 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.

"X-cera Pre-shaded Zirconia Blanks" is supplied in different shapes, such as blocks, discs, rods, or customer ordered shapes. It is also supplied in the combinations of forty nine different colors. The different colors are originated from the different constituent of color additives (such as Fe_2O_3, Er_2O_3).

5.7 Indications for Use:

X-cera Pre-shaded Zirconia Blanks are intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist. All blanks are processed through dental laboratories or by dental professionals

5.8 Summary of Device Testing:

Bench testing was performed per ISO 6872:2015 and internal procedures to ensure that the "X-cera Pre-shaded Zirconia Blanks" 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.

5.9 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	Predicate Device (K093560)
Indication for Use	X-cera Pre-shaded Zirconia Blanks are Intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist. 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 ($ZrO_2 + Y_2O_3 + HfO_2 + Al_2O_3$)≥ 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 nine colors	None
Sterile	Non-sterile	Non-sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. The only minor difference is that the predicate device has no color, while our devices in submission have pre-shaded series of forty nine different colors.

The different colors are originated from the different constituent of color additive (such as Fe_2O_3, Er_2O_3).

These differences do not raise any concerns, demonstrated by biocompatibility study.

5.10 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, and 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, "X-cera Pre-shaded Zirconia Blanks" manufactured by "DONGGUAN XIANGTONG CO., LTD." meet requirements per ISO 6872 and ISO 10993-1. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses. The test results are also comparable to the predicate device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "X-cera Pre-shaded Zirconia Blanks" and its predicate devices have the identical indications for use, similar composition and biocompatibility, similar manufacturing process, and similar performance.

The difference between the "X-cera Pre-shaded Zirconia Blanks" and their predicate device do not raise any question regarding its equivalence.

"X-cera Pre-shaded Zirconia Blanks", as designed and manufactured, is equivalent to its predicate device, and therefore is substantially equivalent as its predicate device.