September 7, 2023

Liaoning UPCERA CO., Ltd
℅ Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K231687
Trade/Device Name: Gradual Dental Zirconia Blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: June 9, 2023
Received: June 9, 2023

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231687

Device Name
Gradual Dental Zirconia Blank

Indications for Use *(Describe)*
The device is indicated for fabrication of anterior and posterior dental restorations using different CAD/CAM or manual machines. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary: K231687

This summary of substantial equivalence information for K231687 is being submitted in accordance with the requirements of 21CFR 807.92

5.1 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

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: September 1, 2023

5.4 Device Name:

Proprietary Name:	Gradual Dental Zirconia Blank
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 Predicate Device Information:

K152175, "Dental Zirconia Blank for Aesthetic Restoration", manufactured by "Liaoning Upcera Co., Ltd." (Primary predicate)

5.6 Device Description:

"Gradual Dental Zirconia Blank" 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 and other oxides. The performance of formed zirconia dental blanks conforms to *ISO 6872, Dentistry, Ceramic Materials.*

"Gradual Dental Zirconia Blank" 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.

"Gradual Dental Zirconia Blank" is supplied in different shapes, such as blocks, discs, rods, or customer ordered shapes. It is also supplied in the combinations of fifty different colors, gradual changing translucencies, and multi-layer aesthetic effect.

The different colors are originated from the different constituent of color additives (such as Fe2O3, Er2O3); the different translucencies are originated from small difference in the amount of Y2 O3, and the multilayer aesthetic effect is originated from the different padding method used in the process of dry pressing.

5.7 Indications for Use:

The device is indicated for fabrication of anterior and posterior dental restorations using different CAD/CAM or manual machines. All blanks are processed through dental labora tories or by dental professionals.

5.8 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 (K152175)
Indication for Use	For fabrication of anterior and posterior d ental restorations using different CAD/C AM or manual machines. All blanks are processed through dental la boratories or by dental professionals.	Is mainly used in prosthetic treatment. While the flexural strength of Dental Zirconia Ceramics 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; While the flexural strength of Dental Zirconia Ceramics after sintering is over 500 MPa, it can be used for veneering, inlay, single crown, and substrate ceramic for three-unit prostheses.
Basic Design	Blocks, disc, and rod	Blocks, disc, and rod
Materials	Zirconia ($ZrO_2 + Y_2O_3 + HfO_2 \geq 98\%$) Inorganic pigments	Zirconia ($ZrO_2 + Y_2O_3 + HfO_2$) $\geq 98\%$) Inorganic pigments
Processing	Sintering at temperature > 1400 °C	Sintering at temperature > 1400 °C
Dimension	Various	Various
Single Use	Yes	Yes
Shade	Fifty colors, one aesthetic effects, and gradual change of translucency effect	Forty six colors, two aesthetic effects: single and multilayer effect, and three translucency effects
Sterile	Non-sterile	Non-sterile

There are wording differences in the indications for use statement between the subject and predicate devices, but the expressed indications essentially have the same meaning. Both devices are intended to be used in the prosthetic treatment and dental restorations. Anterior and posterior dental restorations (as stated for the subject device) include veneering, inlay, single crown, and substrate ceramic for multiple unit prostheses (as stated for the predicate device).

Our device is also essentially identical to the predicate device in terms of design, material, and processing between our device and the predicate devices. The minor differences do not raise any safety and effectiveness concerns.

5.9 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, thermal expansion,

chemical solubility, and flexural strength of the subject device are very similar to the predicate device.

Since “Gradual Dental Zirconia Blank” uses the same material, same composition, same manufacture process as its predicate device, K152175, the biocompatibility of the subject device has been established.

5.10 Summary of Non-Clinical Testing:

Bench testing was performed per ISO 6872:2008 and internal procedures to ensure that the “Gradual Dental Zirconia Blank” 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.

5.11 Summary of Clinical Study:

Clinical Study is not performed for this device.

5.12 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that “Gradual Dental Zirconia Blank” and its predicate devices have similar indications for use, similar composition, and biocompatibility, similar manufacturing process, and similar performance.

The difference between the “Gradual Dental Zirconia Blank” and their predicate device do not raise any question regarding its equivalence.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the subject device is respectively substantially equivalent to the predicate device.