January 9, 2026

Liaoning Upcera Co., Ltd.
% Charles Shen
Vice President
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K253973
Trade/Device Name: Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 11, 2025
Received: December 11, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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Michael E. Adjodha, MChE, RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253973

Please provide the device trade name(s).

Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253973

510(k) Summary

This summary of substantial equivalence information for K253973 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: December 5, 2025

5.4 Device Name:

Proprietary Name:	"Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series"
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:

(1) K231687, "Gradual Dental Zirconia Blank", manufactured by "Liaoning Upcera Co., Ltd."

5.6 Device Description:

"Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series" are 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 $ZrO_2 + Y_2O_3 + HfO_2 + Fe_2O_3 + Er_2O_3$. The performance of formed zirconia dental blanks conforms to *ISO 6872, Dentistry, Ceramic Materials.*

"Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series" are 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 - GT(F) P1, GT(F) P2, and SP Series" are different from the predicate device as they have different manufacture process. GT(F) P1 and GT(F) P2 series use six-layer padding process to produce multi-layer aesthetic effect, while the SP series does not use padding process, produce single aesthetic effect.

GT(F) P1 and SP series have Flexural Strength of >800 MPA, They belong to Type II, Class 5 ceramics per ISO 6872.

GT(F) P2 series have Flexural Strength of >500 MPa, They belong to Type II, Class 4(a) ceramics per ISO 6872.

"Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series" are supplied in different shapes, such as blocks, discs, rods, or customer ordered shapes. It is also supplied in the combinations of fifty different colors.

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_2O_3, and the multilayer aesthetic effect is originated from the different padding method used in the process of dry pressing.

The GT(F) P1 and GT(F) P2 series are supplied in gradual changing translucencies, and multi-layer aesthetic effect. The SP series are supplied with no gradual changing translucencies, and in single-layer aesthetic effect.

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 (K231687)
Indication for Use	For fabrication of anterior and posterior dental restorations using different CAD/C AM or manual machines. All blanks are processed through dental laboratories or by dental professionals.	For fabrication of anterior and posterior dental restorations using different CAD/C AM or manual machines. All blanks are processed through dental laboratories or by dental professionals.
Basic Design	Blocks, disc, and rod	Blocks, disc, and rod
Materials	Zirconia ($ZrO_2 + Y_2O_3 + HfO_2 \geq 98\%$) 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	Fifty colors
Flexural Strength	For GT(F) P1 and SP series: >800 MPA For GT(F) P2 series: >500 MPa	For GT(F) series: >800 MPA For GT(E) series: >500 MPa
Aesthetic Effect	For GT(F) P1 and GT(F) P2 series: Multilayer aesthetic effect For SP series: Single layer aesthetic effect	One aesthetic effects: Multilayer aesthetic effect
Translucency Effect	For GT(F) P1 and GT(F) P2 series: Each blank has gradual change of translucency effect from low to high, which is similar to nature tooth. For SP series: No translucent effect	Each blank has gradual change of translucency effect from low to high, which is similar to nature tooth.

Sterile	Non-sterile	Non-sterile

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 Summary of Non-Clinical Testing:

Bench testing was performed per ISO 6872 to ensure that the "Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series" met its specifications. All tests were verified to meet acceptance criteria. Test results on radioactivity, thermal expansion, chemical solubility, and flexural strength of the subject device are very similar to the predicate device.

Biocompatibility assessment was performed to verify the equivalence of the materials that are used.

5.10 Summary of Clinical Study:

Clinical Study is not performed for this device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "Gradual Dental Zirconia Blank - GT(F) P1, GT(F) P2, and SP Series" 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 - GT(F) P1, GT(F) P2, and SP Series" 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.