March 31, 2023

Topzir Biotech Co., Ltd
% Shanfeng Jiang
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town
Huangpu District, Guangzhou City, Guangdong 510663
China

Re: K230003
Trade/Device Name: Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 3, 2023
Received: January 3, 2023

Dear Shanfeng Jiang:

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,

Bobak Shirmohammadi -S

For 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)*

K230003

Device Name

Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

Indications for Use *(Describe)*

Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling 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.

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Section 5 - 510(k) Summary **K230003**

Date of Summary Preparation: March 14, 2023

1. Submitter's Identifications

Submitter's Name: Topzir Biotech Co., Ltd
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2. Correspondent's Identifications

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3. Name of the Device

Device Classification Name: Powder, Porcelain
Regulation Description: Porcelain powder for clinical use
Trade Name: Topzir Dental Zirconia Blank &Dental Zirconia Pre-Shaded Blank
Model: HT-plus, ST, ST-C, ST-ML, ST PLUS, ST PLUS-C, ST PLUS-ML, 3D-pro-ML, TT, TT-C, TT-ML
Regulation Medical Specialty: Dental
Review Panel: Dental
Product Code: EIH
Regulation Number: 21 CFR 872.6660
Device Classification: Class II

4. The Predicate Devices

Predicate device: K141724 Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank (Primary Predicate)
Liaoning Upcera Company Limited

5. Device Description

Topzir Dental Zirconia Blank are derived from zirconia powder that has been processed into their final shapes. These blanks are then being further fabricated into all-ceramic restorations such as crowns, bridges, veneers, inlay/onlay. The zirconia powder is composed of ZrO_2+ Y_2O_3+ HfO_2+ Al_2O_3 with its composition conforms to ISO 13356, *Implants for surgery – Ceramic materials based on yttriastabilized tetragonal zirconia (Y-TZP)*. The performance of the dental blanks conforms to ISO 6872, *Dentistry — Ceramic materials.*

Topzir Dental Zirconia Pre-Shaded Blank are derived from the same Zirconia powder as the regular Dental Zirconia Blank with the addition of very small amount of inorganic pigments before the composite material is processed into their final net shapes. These blanks are then being further fabricated into all-ceramic restorations such as crowns, bridges, veneers, inlay/onlay. The purpose of the inorganic pigments is to generate the color on the prosthetic dental devices, after sintering at dental labs, that matches natural color of patient's teeth. The performance of the dental blanks conforms to ISO 6872, *Dentistry — Ceramic materials*.

6. Intended Use of Device

Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number	K230003	K141724	------
Product Code	EIH	EIH	Same
Proprietary Name	Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	------
Model:	HT-plus, ST, ST-C, ST-ML, ST PLUS, ST PLUS-C, ST PLUS-ML, 3D-pro-ML, TT, TT-C, TT-ML	------	------
Manufacturer	Topzir Biotech Co., Ltd	Liaoning Upcera Company Limited	------

Indications for Use	Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed through dental laboratories or by dental professionals.	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are processed though dental laboratories or by dental professionals.	Same
Basic design	Blocks, and rods	Blocks, disc, and rod	Same
Materials	Regular: Zirconia (ZrO_2+ Y_2O_3+ HfO_2+ Al_2O_3≥99.0%) Pre-shaded: Zirconia (ZrO_2+ Y_2O_3+ HfO_2+ Al_2O_3≥99.0%) Inorganic pigments (Fe_2O_3, Er_2O_3 and MnO ＜2.0%)	Regular: Zirconia (ZrO_2+ Y_2O_3+ HfO_2+ Al_2O_3≥99.0%) Pre-Shaded: Zirconia (ZrO_2+ Y_2O_3+ HfO_2+ Al_2O_3≥98.0%) Inorganic pigments (Fe_2O_3, Pr_2O_3, and Er_2O_3 ＜2.0%)	Similar[1]
Processing	Sintering at temperature: ＞ 1450℃	Sintering at temperature: ＞ 1500℃	Similar[2]
Dimension	Various	Various	Same
Single Use	Yes	Yes	Same
Color	None, and Pre-shaded (for pre-shaded series)	None, and Pre-shaded (for pre-shaded series)	Same
Sterile	Non-sterile	Non-sterile	Same

The proposed device is essentially identical to the predicate devices in terms of indication for use, design between our device and the predicate devices. The minor

differences are that as below:

Note 1: Zirconia (ZrO_2+ Y_2O_3+ HfO_2+ Al_2O_3) of proposed device which is not less than 99.0% is higher than that of the predicate device. The three inorganic pigments of the proposed device contain Fe_2O_3, Er_2O_3 and MnO, while those of the predicate device are Fe_2O_3, Pr_2O_3, and Er_2O_3. These are minor differences and the biocompatibility testing of the overall proposed device passed.

Note 2: Processing (Sintering at temperature) of the proposed device is slightly lower 5℃ than that of the predicate device. This is minor difference and the performance testing of the proposed device passed.

8. Summary of Non-Clinical Testing

Bench testing was performed per ISO 6872:2015 and internal procedures to ensure that the Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank met its specifications. All tests were verified to meet acceptance criteria. Test results on radioactivity, flexural strength, chemical solubility, linear thermal expansion coefficient, freedom from extraneous materials, uniformity, shrinkage factor, pre-sintered density, sintered density, and fracture toughness of the subject device are very similar to predicate device. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

According to ISO 10993-1:2018 and ISO ISO7405:2018, we evaluated and conducted the compatibility test for the proposed device. The following table shows the biocompatibility testing results.

Table 2 Biocompatibility testing

Item	Proposed device	Result
Cytotoxicity (ISO 10993-5:2009)	Under the conditions of this study, the test article was non cytotoxic for 2 h and 24 h in the filter diffusion method. Under the conditions of this study, the test article was accepted in the agar diffusion method. Under the conditions of this study, the test article has no potential toxicity to L-929 cells.	Pass
Oral Mucosa Irritation (ISO 10993-23:2021)	The test article has no potential oral mucosa irritation in the Syrian hamsters.	Pass
Skin Sensitization Test (ISO 10993-10:2021)	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	Pass
Subacute Toxicity Test (ISO 10993-11:2017)	The test result showed that the test article did not induce subacute systemic toxicity in rats under this condition .	Pass
Subacute Systemic Toxicity Test (ISO 10993-11:2017)	The test result showed that the test article did not induce subacute systemic toxicity in rats under this condition.	Pass

Acute Systemic Toxicity (ISO 10993-11:2017)	The test article showed no evidence of causing acute system toxicity in the ICR mice.	Pass
In Vitro Mammalian Cell Gene Mutation Test (ISO 10993-3:2014)	Under the conditions of this study, the test article is considered non-mutagenic.	Pass
In vitro Mammalian Chromosome Aberration Test (ISO 10993-3:2014)	Under the conditions of this study, the test article did not induce structural chromosome aberrations in cultured CHL cells.	Pass
Bacterial Reverse Mutation Test (ISO 10993-3:2014)	Under the conditions of this study, the number of reverting colonies in the test article group is not equal to or greater than 2 times that of the spontaneous control, so the test article have no potential mutagenesis.	Pass
Muscle Implant (ISO 10993-6:2016)	The test result showed that the test article did not induce local effects after implantation of biomaterials in rabbits under this condition.	Pass

Note: Testing were Performed on Dental Zirconia Blank ST PLUS with Pre-Shaded powder C4 (C4 is deep color, see the VITA 16 color shade guide picture) to cover the regular and pre-shaded zirconia blanks.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that subject device Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank performs as well as or better than the legally marketed predicate device K141724 Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank. Topzir Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank is substantial equivalent to the legally marketed predicate device K141724 Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank.