May 13, 2020

3DBioCAD
% Stuart Goldman
Sr. Consultant RA/QA
EMERGO Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K193055
Trade/Device Name: Purzir Dental Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: February 7, 2020
Received: February 13, 2020

Dear Stuart Goldman:

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 “Nandu” 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)*
K193055

Device Name
Pürzir Dental Zirconia

Indications for Use *(Describe)*
Pürzir Dental Zirconia blanks 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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510(k) Summary

Pürzir Dental Zirconia

1. Submission Sponsor

3DBioCAD
1525 N 4th St.
Renton, WA 98057
USA
Contact: Gyu D. Cho
Title: President

2. Submission Correspondent

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Contact: Stuart R. Goldman
Title: Sr. Consultant RA/QA

3. Date Prepared

May 11, 2020

4. Device Identification

Trade/Proprietary Name:	Pürzir Dental Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use
Regulation Number:	CFR 872.6660
Product Code:	EIH
Class:	II
Classification Panel:	Dental

5. Legally Marketed Predicate Device

Device name:	Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank
510(k) number:	K141724
Manufacturer:	Liaoning Upcera Co., Ltd.

6. Indication for Use

Pürzir Dental Zirconia blanks 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. Device Description

Pürzir Dental Zirconia are disc shaped zirconia oxide blanks made available in different versions and chemical compositions of various colors, shades and dimensions and sold to dental labs that will further process the discs by milling them to make final dental restorations such as crowns, bridges, veneers, inlays and on lays based on the anatomical rendering of the patient's teeth using Computer Aided Drafting / Computer Aided Machining (CAD / CAM) equipment. The subject device is made available in six versions: 1. HS (High Strength), 2. HT (High Translucent), 3. HT Plus (High Translucent Plus), 4. ST (Super Translucent), 5. MMT x2 (Max Multi Translucent), and 6. MMT Plus x2 (Max Multi Translucent Plus).

8. Substantial Equivalence Comparison

Table 5-1 compares Pürzir Dental Zirconia discs to the predicate device (K141724) with respect to regulatory information, intended use, indications for use, technological characteristics, and non-clinical performance testing and provides detailed information regarding the basis for the determination of substantial equivalence between the subject and predicate device.

Table 5-1 – Substantial Equivalence Comparison of Pürzir Dental Zirconia vs. Predicate Device (K141724)

Attributes	Subject Device	Predicate Device	Similarities / Differences
Device Name	Pürzir Dental Zirconia	Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank	-
Manufacturer	3DBioCAD	Liaoning Upcera	-
510(k) #	K193055	K141724	-
Product Code	EIH	EIH	Same
Regulation	CFR 872.6660	CFR 872.6660	Same
Regulation Name	powder, porcelain	powder, porcelain	Same
Class	II	II	Same
Review Panel	Dental	Dental	Same
Indications for Use	Pürzir Dental Zirconia blanks 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 and 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.	Same
Form	Disc form.	Block, disc and rod form.	The subject device is only

Attributes	Subject Device	Predicate Device	Similarities / Differences
			made available in disc form.
Dimensions	Various	Various	Similar
Material	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%)	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%)	Same
Color	None, and Pre-shaded (for pre-shaded series).	None, and Pre-shaded (for pre-shaded series).	Same
Processing	Sintering at temperature > 1500 °C	Sintering at temperature > 1500 °C	Same
Conditions of Use	Professional use for the fabrication of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers.	Professional use for the fabrication of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers.	Same
Single Use	Yes	Yes	Same
Supplied Sterile	No	No	Same
Packaging	Single blank (disc) per box.	Single blank (disc) per box.	Same
Shelf Life	5 years from date of manufacture	5 years from date of manufacture	Same
Biocompatibility Testing	Tested to ISO 10993-1	Tested to ISO 10993-1	Conforms
Performance Testing	Tested to ISO 6872	Tested to ISO 6872	Conforms

9. Summary of Non-Clinical Performance Testing

As part of demonstrating substantial equivalence of Pürzir Dental Zirconia discs to the predicate device, 3DBioCAD tested final finished samples of their device in accordance with the applicable parts of the following FDA guidance documents and voluntary recognized consensus standards. Results confirm that the design inputs and performance specifications for the subject device have been met.

- Biocompatibility Testing:
    - FDA Guidance Document – *Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process*

- ISO 10993-1, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*:
  - ISO 10993-3 (genotoxicity)
  - ISO 10993-5 (cytotoxicity)
  - ISO 10993-10 (skin sensitization and irritation)
  - ISO 10993-11 (toxicity)

- Non-Clinical Performance Testing:
  - ISO 6872, *Dentistry – Ceramic materials*
    - chemical solubility
    - flexural strength
    - coefficient of linear thermal expansion

10. Clinical Testing

Clinical testing on the subject device have not been performed.

11. Statement of Substantial Equivalence

Pürzir Dental Zirconia has the same intended use and indications for use as Upcera Dental Zirconia Blank and Dental Zirconia Pre-Shaded Blank (K141724). Any minor differences in the technological features of the subject device when compared to the predicate device have been successfully evaluated through non-clinical performance testing and other verification and validation activities such that the information submitted to the FDA demonstrates that Pürzir Dental Zirconia is substantially equivalent to the predicate device.