November 15, 2021

Bloomden Bioceramics (HuNan) Co., Ltd
Grace Liu
Consultant
Shenzhen Joyantech Consulting Co. Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518000
CHINA

Re: K212765
Trade/Device Name: Bloomden 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: August 23, 2021
Received: August 31, 2021

Dear Grace Liu:

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, 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)*

K212765

Device Name
Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

Indications for Use *(Describe)*
HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872.

UT, UT-C, UT-ML are intended for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The products have to be categorized as class 4 according to ISO 6872.

The products are suitable for CAD/CAM milling machines which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.

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.

K212765 510(k) Summary

1. Contact Details

1.1 Applicant information

Applicant Name	Bloomden Bioceramics (HuNan) Co., Ltd
Address	No.301, 5th Building, Hi-tech Int'l Enterprise Port, LianDong U Valley, Linyu Rd, Dongfanghong Street, Hi-tech Development Zone, Changsha, HuNan, China
Contact person	Shengyong Liao
Phone No.	+86-15874253042
E-mail	819441390@qq.com
Date Prepared	2021-10-14

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86-755-86069197
Contact person	Grace Liu; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Common name	Dental Zirconia Ceramics
Model	HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, UT, UT-C, UT-ML
Classification	Ⅱ
Classification name	Porcelain powder for clinical use
Product code	EIH
Regulation No.	21 CFR 872.6660

3. Legally Marketed Predicate Device

Trade Name	PRETTAU®, ICE and Z-WHITE zirconia blanks
510(k) Number	K183304
Product Code	EIH
Manufacturer	ZIRKONZAHN SRL

4. Device Description

Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank is composed of yttria-stabilized zirconia. The yttria-stabilized zirconia has a long history of safe use in dentistry.

Bloomden Dental Zirconia Blank is white, and it is composed of ZrO_2+HfO_2+Y_2O_3 and additional other oxides. Bloomden Dental Zirconia Pre-Shaded Blank is color (containing 20 available Vita shades), and it contains not only the ingredients same as the white zirconia blank but also very small amount of additional inorganic pigments (Fe_2O_3+Er_2O_3+MnO). The inorganic pigments generate the color on the restorations, after sintering at dental labs, that matches natural color of patient's teeth. And there are two color representations (i.e. monolayer and multilayer) for the color zirconia blank.

The proposed device is provided in various translucency (High-plus Translucency, Super Translucency, Super-high Translucency, Ultra Translucency and 3D-Pro-ML). It also offers various shapes and dimensions suitable for different milling systems.

The proposed device is processed into the dental restorations such as crowns, bridges, veneers, inlays and onlays based on the anatomical rendering of the patient's teeth using CAD/CAM (computer aided design / computer aided manufacturing) method.

The performance of the proposed device conforms to ISO 6872:2015 Dentistry: Ceramic Materials.

The proposed device is a single-use device, and provided non-sterile.

5. Intended Use/Indication for Use

HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872.

UT, UT-C, UT-ML are intended for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The products have to be categorized as class 4 according to ISO 6872.

The products are suitable for CAD/CAM milling machines which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.

6. Substantial Equivalence Comparison

Table 1 Substantial Equivalence Comparison

Comparison item	Proposed Device	Predicate Device (K183304)	Comment
Manufacturer	Bloomden Bioceramics (HuNan) Co., Ltd	ZIRKONZAHN SRL	None

Product Name	Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	PRETTAU®, ICE and Z-WHITE zirconia blanks	None
Product Code	EIH	EIH	Same
Regulation Number	21 CFR § 872.6660	21 CFR § 872.6660	Same
Classification	Class II	Class II	Same
Prescription Use	Yes	Yes	Same
Indications for Use	HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872. UT, UT-C, UT-ML are intended for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The products have to be categorized as class 4 according to ISO 6872. The products are suitable for CAD/CAM milling machines which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.	Prettau®, Prettau® 2, Prettau® 2 Coloured, Prettau® 2 Dispersive, ICE Translucent, ICE Premium, ICE Abutment, ICE Translucent Plus, ICE Translucent Plus Coloured, ICE Translucent Plus Dispersive and Z-White are intended for the manufacturing of metal-free partial and single crowns, full arch occlusally screwed bridges, inlays, onlays, and veneers, full contour restorations as well as reduced structures in combination with veneering ceramics. The products are categorized into class 5 according to ISO 6872. Prettau® 3, Prettau® 3 Coloured, Prettau® 3 Dispersive, Prettau® 4 Anterior®, Prettau® 4 Anterior® Coloured and Prettau® 4 Anterior® Dispersive are destined for the manufacturing of metal-free partial and single crowns, max. 3-unit bridges, inlays, onlays and veneers, full contour restorations as well as for reduced structures in combination with veneering ceramics and implant superstructures for 3-unit restorations in the anterior and posterior tooth region. The	Similar

		products have to be categorized as class 4 according to ISO 6872. The products have been developed for use with Colour Liquid, ICE Zirkon Ceramics, ICE Zirkon Stains and ICE Zirkon Stains 3D. Observe the relative instructions of use when using these products. The blocks are suitable for all milling units, which are able to process presintered zirconia and which have the proper clamping device for the corresponding block.	
Class (per ISO 6872:2015)	Class 4 UT, UT-C, UT-ML Class 5 HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML	Class 4 Prettau® 3, Prettau® 4 Anterior Class 5 Prettau®, Prettau® 2, ICE group, Z-White	Same
Composition	Based on yttria-stabilized zirconia	Based on yttria-stabilized zirconia	Similar
Color	White, Color	White, Color	Similar
Intended User	Professional dental technicians	Professional dental technicians	Same
Single Use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Physical Properties	Conform to ISO 6872:2015	Conform to ISO 6872:2015	Same
Uniformity	Uniform	Uniform	Same
Freedom from extraneous materials	Free from extraneous materials	Free from extraneous materials	Same
Radioactivity	$\leqslant$1.0 Bq·g^{-1}	$\leqslant$1.0 Bq·g^{-1}	Same
Flexural strength	UT, UT-C, UT-ML: ≥ 500 MPa HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML: ≥ 800 MPa	Prettau® 3, Prettau® 4 Anterior: 600 MPa Prettau®, Prettau® 2, ICE group, Z-White: ≥ 900 MPa	Similar
Chemical solubility	$<$100 μg.cm^{-2}	$<$100 μg.cm^{-2}	Same

Linear thermal expansion coefficient	$(10.5\pm0.5)\times10^{-6}K^{-1}$	Not publicly available	Different
Shrinkage factor	1.243±0.002	Not publicly available	Different
Biocompatibility	Conform to ISO 7405:2018	Conform to ISO 10993-1	Similar
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

The proposed device has the similar indication for use as the predicate device as well as comparable technical and biocompatibility properties and characteristics, and the minor differences don't raise any additional questions for safety and effectiveness, therefore, the proposed device is substantially equivalent to the predicate device.

7. Non-clinical Testing

The performance tests were performed according to *ISO 6872:2015 Dentistry - Ceramic materials*, and the test results showed that the proposed device meets the requirements specified in the standard (see Table 2).

Table 2 Summary of Performance Testing

Test Item	Test Results		Judgment
	UT, UT-C, UT-ML	HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML	
Uniformity	Uniform	Uniform	Pass
Freedom from extraneous materials	Free from extraneous materials	Free from extraneous materials	Pass
Radioactivity	$<0.02\ Bq\cdot g^{-1}$	$<0.02\ Bq\cdot g^{-1}$	Pass
Flexural strength	864.3 MPa	1238.2 MPa	Pass
Chemical solubility	$13.5\ \mu g.cm^{-2}$	$11.8\ \mu g.cm^{-2}$	Pass
Linear thermal expansion coefficient	$10.0\times10^{-6}K^{-1}$	$10.5\times10^{-6}K^{-1}$	Pass
Shrinkage factor	1.244, 1.243, 1.243	1.244, 1.245, 1.241	Pass

The biocompatibility tests were performed according to *ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* (see Table 3), and the test results showed that the proposed device has no biocompatibility issues.

Table 3 Summary of Biocompatibility Testing

Biological Endpoint	Reference	Test Result
Cytotoxicity	ISO 10993-5:2009	No cytotoxicity under the conditions of the study
	6.2 of ISO 7405:2018	No cytotoxicity under the conditions of the study
	6.3 of ISO 7405:2018	No cytotoxicity under the conditions of the study
Skin Sensitization	ISO 10993-10:2010	No skin sensitization under the conditions of the study
Oral Mucosa Irritation	ISO 10993-10:2010	No oral mucosa irritation under the conditions of the study
Acute Systemic Toxicity	ISO 10993-11:2017	No acute systemic toxicity under the conditions of the study
Subacute Systemic Toxicity	ISO 10993-11:2017	No subacute systemic toxicity under the conditions of the study
Subchronic Systemic Toxicity	ISO 10993-11:2017	No subchronic systemic toxicity under the conditions of the study
Genotoxicity	ISO 10993-3:2014	No genotoxicity under the conditions of the study
Implantation	ISO 10993-6:2016	No local effects under the conditions of the study

The results of the non-clinical testing demonstrate that the proposed device is equivalent to the predicate device.

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusions

The results of comparing the design specifications and non-clinical testing between the proposed device and the legally marketed predicate device (K183304) show that they are Substantially Equivalent (SE).