March 30, 2026

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: K260370
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: February 5, 2026
Received: February 5, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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.	K260370

Please provide the device trade name(s).

Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

Please provide your Indications for Use below.

HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 14-unit teeth, i.e. the manufacturing of

_ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);

_ anatomically reduced and fully anatomical (monolithic) bridges (up to 14 units) in the anterior and posterior tooth range.

UT, UT-C, UT-ML, UTP, UTP-C, UTP-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 3-unit teeth, i.e. the manufacturing of

_ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);

_ anatomically reduced and fully anatomical (monolithic) bridges (up to 3 units) in the anterior and posterior tooth range.

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)

K260370

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 Changsha, HuNan 410000 China
Contact person	Shengyong Liao
Phone No.	+86-15874253042
E-mail	819441390@qq.com
Date Prepared	2026-02-05

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 518000 China
Phone No.	+86-755-86069197
Contact person	Grace Liu
Contact person's e-mail	grace@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, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML, UTP, UTP-C, UTP-ML
Classification	II
Classification name	Powder, porcelain

Product code	EIH
Regulation No.	21 CFR 872.6660

3. Legally Marketed Predicate Device

Trade Name	Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
510(k) Number	K212765
Product Code	EIH
Manufacturer	Bloomden Bioceramics (HuNan) Co., Ltd

4. Device Description

Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank (including HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, UT, UT-C, UT-ML) has been cleared in K212765. The following changes have been made in this submission:

(1) Added several new specifications to HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, UT, UT-C, UT-ML;

(2) Added 11 new models (HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML, UTP, UTP-C, UTP-ML) made from zirconia powders from another supplier.

(3) Detailed the intended use.

(4) Claimed a shelf life of 5 years.

(5) Updated Instructions for Use.

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/Co_3O_4). The inorganic pigments generate the color on the restorations, after sintering in dental labs, matching 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. 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 6872:2024 Dentistry - Ceramic Materials.

The proposed device is a single-use device, and provided non-sterile. The shelf life is 5 years.

5. Intended use

The blanks are intended to be processed into the custom-made dental restorations such as crowns, bridges, veneers, inlays and onlays.

6. Indications for use

HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 14-unit teeth, i.e. the manufacturing of

_ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);

_ anatomically reduced and fully anatomical (monolithic) bridges (up to 14 units) in the anterior and posterior tooth range.

UT, UT-C, UT-ML, UTP, UTP-C, UTP-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 3-unit teeth, i.e. the manufacturing of

_ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers);

_ anatomically reduced and fully anatomical (monolithic) bridges (up to 3 units) in the anterior and posterior tooth range.

7. Substantial Equivalence Comparison

Comparison Item	Proposed Device	Predicate Device (K212765)	Comment
Manufacturer	Bloomden Bioceramics (HuNan) Co., Ltd	Bloomden Bioceramics (HuNan) Co., Ltd	Same
Product Name	Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank	Same
Product Code	EIH	EIH	Same
Regulation Number	21 CFR § 872.6660	21 CFR § 872.6660	Same
Classification	Class II	Class II	Same
Prescription	Yes	Yes	Same

Use			
Intended use	The blanks are intended to be processed into the custom-made dental restorations such as crowns, bridges, veneers, inlays and onlays.	The blanks are intended to be processed into the custom-made dental restorations such as crowns, bridges, veneers, inlays and onlays.	Same
Indications for Use	HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 14-unit teeth, i.e. the manufacturing of _ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers); _ anatomically reduced and fully anatomical (monolithic) bridges (up to 14 units) in the anterior and posterior tooth range. UT, UT-C, UT-ML, UTP, UTP-C, UTP-ML are indicated for the treatment of partial or total loss of anatomical crown in the anterior and posterior tooth regions, from single crown to up to 3-unit teeth, i.e. the manufacturing of _ anatomically reduced and fully anatomical (monolithic) crowns in the anterior and posterior tooth range (e.g. single-tooth crowns, inlays, onlays, veneers); _ anatomically reduced and fully anatomical (monolithic) bridges (up to 3 units) in the anterior and posterior tooth range.	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.	Similar

Class (per ISO 6872)	Class 4 UT, UT-C, UT-ML, UTP, UTP-C, UTP-ML Class 5 HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML	Class 4 UT, UT-C, UT-ML Class 5 HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML	Same
Composition	Based on yttria-stabilized zirconia	Based on yttria-stabilized zirconia	Same
Color	White, Color	White, Color	Same
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 6872:2024	Conform to ISO 6872:2015	Similar
Flexural strength	Class 4: UT, UT-C, UT-ML, UTP, UTP-C, UTP-ML: ≥ 500 MPa Class 5: HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML: ≥ 800 MPa	Class 4: UT, UT-C, UT-ML: ≥ 500 MPa Class 5: HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML: ≥ 800 MPa	Same
Biocompatibility	Conform to ISO 7405:2018	Conform to ISO 7405:2018	Same
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

In conclusion, the proposed device has the same intended use and similar indication for use as the predicate device. And it also has the similar technical characteristics to the predicate device. The differences don't raise any additional questions for safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.

8. Non-clinical Testing

Non-clinical tests were conducted to demonstrate the safety and effectiveness of Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank and the substantial

equivalence to the predicate device.

- **Biocompatibility Testing**

The biocompatibility were evaluated according to *ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*.

The models made from different zirconia powders were evaluated separately:

- For HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, UT, UT-C, UT-ML:

  The biocompatibility testing was not conducted on these 11 models, because their formulation and processing are exactly the same to the devices cleared in K212765, the only difference is that several new specifications are introduced, but this change in shape and dimensions is physical, not affecting the biocompatibility.

- For HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML, UTP, UTP-C, UTP-ML:

  The biocompatibility testing was conducted on the representative model of these 11 models, see the following table for details:

Biological Endpoint	Reference	Test Results
Cytotoxicity	ISO 10993-5:2009	No cytotoxicity under the conditions of the study.
	ISO 7405:2018, 6.2	No cytotoxicity under the conditions of the study.
	ISO 7405:2018, 6.3	No cytotoxicity under the conditions of the study.
Skin Sensitization	ISO 10993-10:2021	No skin sensitization under the conditions of the study.
Oral Mucosa Irritation	ISO 10993-23:2021	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.
Implantation	ISO 10993-6:2016	No local effects under the conditions of the study.
Chemical Characterization and Toxicological Evaluation	ISO 10993-17:2023, ISO 10993-18:2020 +A1:2023	All elements greater than or equal to the method detection limit (MDL) and all compounds greater than or equal to AET were identified, and their MOS values were all greater than 1.0 for intended patient populations. It is reasonably anticipated that the toxicological risks of extractables

		(including Subacute/Subchronic Systemic Toxicity and Genotoxicity) are acceptable in this product.

- **Performance Testing**

The performances were evaluated according to *ISO 6872:2024 Dentistry - Ceramic materials*, including Uniformity, Freedom from extraneous materials, Radioactivity of dental ceramic, Flexural strength, Chemical solubility, Linear thermal expansion coefficient and Shrinkage factor.

The models made from different zirconia powders were evaluated separately:

- For HT-plus, ST, ST-C, ST-ML, SHT, SHT-C, SHT-ML, 3D-Pro-ML, UT, UT-C, UT-ML:

  The performance testing was not conducted on these 11 models. Because their formulation and processing are exactly the same to the devices cleared in K212765, the only difference is that several new specifications are introduced, but this change in shape and dimensions does not affect the performance items specified in ISO 6872.

- For HTP-plus, STP, STP-C, STP-ML, SHTP, SHTP-C, SHTP-ML, 3DP-Pro-ML, UTP, UTP-C, UTP-ML:

  The performance testing was conducted on the representative model of these 11 models. The test results demonstrate that the proposed device met the requirements of ISO 6872:2024.

- **Shelf Life**

Accelerated aging testing was performed separately on the representative models made from different zirconia powders to assure the shelf-life of 5 years in accordance with ASTM F1980-21.

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusions

The results of comparing the design specifications and non-clinical testing between the proposed device and the legally marketed predicate device (K212765) show that they are Substantially Equivalent (SE).