May 22, 2019

Baot Biological Technology Co., LTD
Liqun Zhu
Quality Manager
Unit 1, Second Floor, No 12 Building, Yujing Industry Zone,
106 Qihao Road, Torch Development District
Zhongshan, 528437 CHINA

Re: K182350
Trade/Device Name: Dental Ceramic
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: February 21, 2019
Received: February 21, 2019

Dear Liqun Zhu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Malvina Eydelman, M.D.
Director
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)*
K182350

Device Name
Dental Ceramic (Model: Metal Ceramic; Zirconia Ceramic)

Indications for Use *(Describe)*
Dental Ceramic is indicated for use for metal-ceramic full veneers and partial veneers and for zirconia full veneers and partial veneers.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K182350

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	BAOT BIOLOGICAL TECHNOLOGY CO.,LTD
Address:	Unit 1, Second Floor, No 12 Building, Yujing Industry Zone, 106 Qihao Road, Torch Development District, Zhongshan City, Guangdong, P.R. China
	Zip Code: 528437
Company Phone No:	+86 760 87893826
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Contact Person:	Liqun Zhu
E-mail:	baotw@baot.biz
Date summary prepared:	August 10, 2018

2. Device Identification

Device Trade Name:	Dental Ceramic (Model: Metal Ceramic; Zirconia Ceramic)
Classification Name	powder, porcelain
Regulation Number:	21 CFR 872.6660
Regulation Name:	Porcelain Powder For Clinical Use
Regulation Class:	II
Product Code:	EIH

3. Predicate Devices

Device Trade Name:	Luminesse Porcelain System
510(k) Number;	K140848
Regulation Name:	Porcelain Powder For Clinical Use
Class:	II
Classification Panel:	Dental
Product Code:	EIH
Regulation Number:	21 CFR 872.6660

4. Device Description

Dental Ceramic divided into two categories: Metal Ceramic; Zirconia Ceramic.

They are used to be made for simulation tooth of human whose ages above 18. After fired, form the whole or part of a dental restoration or prosthesis. It is made by Aluminium oxide(Al_2O_3), Silicon dioxide (SiO_2), Potassium carbonate (K_2CO_3), Sodium carbonate (Na_2CO_3), Calcium oxide (CaO), Zirconium dioxide (ZrO_2),

Metal Ceramic :a complete metallic substructure of Dental Ceramic are Glaze separated two parts-metal and ceramic, which is made of metal alloys and whose inner is a framework. The materials within the metallic is broadly divided into three categories: precious metal, semi-precious metal alloys and non-precious metal alloys, being usually called inner alloy crown.

Zirconia Ceramic : A complete Zirconia Ceramics are separated two parts-Zirconia coping and porcelain layer (Dentin layer and Enamel layer), as shown in the figure, the innermost layer of dental ceramic is Zirconia coping which is a framework. It has a positive impact on bearing and combining closely with the dentin layer.

5. Intended Use / Indications for Use

Dental Ceramic is indicated for use for metal-ceramic full veneers and partial veneers and for zirconia full veneers and partial veneers.

6. Substantial Equivalence

A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows.

Feature	Our device	Luminesse Porcelain (K140848)	Comments
Indications For Use:	Dental Ceramic is indicated for use for metal-ceramic full veneers and partial veneers and for zirconia full veneers and partial veneers.	The Luminesse Porcelain System is dental porcelain material to be used in conjunction with metal, zirconia, or pressable ceramic framework in the construction of crowns and/or bridgework and veneers.	Different The description of the intended use is different, but it is the same as product form, the actual use and methods, and the change of descrption for IFU does not cause unknown safety problems.
Chemical composition	Aluminium oxide(Al2O3), Silicon dioxide (SiO2), Potassium carbonate (K2CO3), Sodium carbonate (Na2CO3), Calcium oxide (CaO), Zirconium dioxide (ZrO2)	Equivalent devices are compared with predicate products (K981490), the comments shows that Most all oxides are present in both Luminesse High-Fusing and Willi Geller Creation CC porcelain, it included varying proportions of silicon dioxide, aluminum dioxide, sodium oxide, potassium oxide, tin oxide, barium oxide and iron oxide. Chemically stable mixed metal oxides, including spinel, baddeleyit, zircon, and periclase phases of zirconium, iron, cobalt, chromium, yttrium, cerium, nickel and zinc oxides, are used in trace amounts for pigmentation. The paste opaques are comprised of ceramic powder fitting this description suspended in glycerol, zinc chloride, sodium acetate, propandiol, and aerosol. The stains are composed of silicon dioxide, alumiun oxide, potassium oxide, tin oxide, barium oxide,	Different The predicate device state that it included varying proportions of silicon dioxide, aluminum dioxide, sodium oxide, potassium oxide, tin oxide, barium oxide and iron oxide. We performed Biocompatibility test and ISO 6872 test, the test result shows that Components of our product met requirements of biocompatibility and performance. The difference does not cause unknown safety problems.

		iron oxide, and calcium oxide, and chemically stable mixed metal oxides for pigmentation.	
Classification Code	21 CFR 872.6660 Product Code: EIH	21 CFR 872.6660 Product Code: EIH	Same
Flexural strength	METAL CERAMIC OPAQUE :98.63MPa DENTINE :98.07Mpa ENAMEL :102.48Mpa ZIRCONIA CERAMIC DENTINE :92.56MPa ENAMEL :98.87MPa	Met the requirements of ISO 6872	The predicate device(K140848) do not list the main technological characteristic in the 510(k) summary, it just state that Bench testing to determine flexural strength, solubility, and glass transition temperature was conducted in accordance with ISO 6872. We also performed the bench test in accordance with ISO 6872. The test results can prove our product met the requirements of ISO 6872, we think the lack of performance data of predicate device do not does not cause unknown safety problems.
Solubility	METAL CERAMIC OPAQUE :15.88μg.cm-2 DENTINE :36.77μg.cm-2 ENAMEL :18.40μg.cm-2 ZIRCONIA CERAMIC DENTINE :18.17μg.cm-2 ENAMEL :28.60μg.cm-2	Met the requirements of ISO 6872	
Glass transition temperature	METAL CERAMIC OPAQUE :575℃ DENTINE : 575℃ ENAMEL : 575℃ ZIRCONIA CERAMIC DENTINE : 590℃ ENAMEL : 590℃	Met the requirements of ISO 6872	
Biocompatibility	Met the requirements of ISO 10993-1,-3,-5,-10,-11, USP40<151>	Components of this product have not changed in any way from the predicate that would adversely affect biocompatibility; therefore,	Different We performed ISO 10993 test to prove

		it is determined that no biocompatibility testing is necessary for this product.	our product's biocompatibility.

7. Biocompatibility Testing

Our product belong to external communicating device which contact dentin more than 30 days, we have conducted biological evaluations based on the requirements of ISO 10993-1 and other similar dental materials, as below :

- Ames Test - ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- In Vitro Cytotoxicity Test - ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Oral MucOsa Irritation - ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Skin sensitization - ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Pyrogen Test - ISO 10993-11 and USP40<151>Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Acute systemic Toxicity Test - ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Subchronic systemic Toxicity Test - ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

8. Performance testing :

Performance testing was conducted in accordance with ISO 6872:2008 Dentistry – Ceramic materials. The Dental Ceramic is classified as a Type I, Class 1 device and met the standard requirements per ISO 6872:2015. We also provided a comparison between ISO 6872:2008 and ISO 6872:2015, effects of changes to materials properties.

9. Conclusions:

It has the same technological characteristics, manufacturing process, and similar intended use, chemical composition, as the predicate devices. Our products are substantially equivalent as its predicate device.