January 31, 2020

Qinhuangdao Audental Metal Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401 CHINA

Re: K192535
Trade/Device Name: Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: November 1, 2019
Received: November 4, 2019

Dear Ray Wang:

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)*

K192535

Device Name
Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia

Indications for Use *(Describe)*

The Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia are intended for use with CAD/CAM technology to produce all ceramic dental restorations (full contour crowns, bridges, inlays, and Veneers) as prescribed by a dentist.

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.

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Tab #8 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192535

1. Date of Preparation

   01/30/2020

2. Sponsor

Qinhuangdao Audental Metal Technology Co., Ltd.

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia
Common Name: Porcelain Powder for Clinical Use
Model(s): DUT and DUTC

Regulatory Information:
Classification Name: Porcelain Powder for Clinical Use
Classification: II;
Product Code: EIH;
Regulation Number: 21 CFR 872.6660；
Review Panel: Dental;

Indications for Use Statement:
The Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia are intended for use with CAD/CAM technology to produce all ceramic dental restorations (full contour crowns, bridges, inlays, and Veneers) as prescribed by a dentist.

5. Device Description

The Dental Zirconia are intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist.

The Dental Zirconia divided into two categories: Unshaded (Model: DUT) and Pre-Shaded (Model: DUTC).

Both Unshaded Dental Zirconia (Model: DUT) and Pre-Shaded Dental Zirconia (Model: DUTC) are available in discs shape, and in various specifications, which are shares same diameter (98 mm) and combinations of height (10-25 mm).
The color model for pre-shaded dental zirconia includes A1; A2; A3; A3.5; B2; C2; D2; 1M1; 1M2; 2L1.5; 2M2; 3M2; 3M3; 4M2; 5M3 for difference color.

Both Unshaded Dental Zirconia (Model: DUT) and Pre-Shaded Dental Zirconia (Model: DUTC) have same base materials and derived from zirconia powder that has been processed via uni-aixial die pressing, followed by isostatic pressing, to achieve various shapes of uniform density and distribution. The ceramic blocks can be fabricated into various prosthetic dental devices.

The zirconia powder of Dental Zirconia is composed of ZrO2+Y2O3+HfO2+Al2O3. The performance of the Dental Zirconia conforms to ISO 6872:2015 Dentistry: Ceramic Materials.

The Dental Zirconia are disposable device, and provided as non-sterile

6. Identification of Primary Predicate Device

Primary Predicate Device:
510(k) Number: K172761
Product Name: New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded)
Manufacturer: Shanghai New Century Dental Materials Co., Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 6872:2015 Dentistry - Ceramic Materials
ISO 10993-3: 2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
ISO 10993-5: 2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2006 Biological evaluation of medical device – Part 11: Tests for systemic toxicity.

The biocompatibility tests conducted on the subject device includes:
Cytotoxicity Testing (ISO 10993-5:2009), Oral Mucosa Irritation Testing (ISO 10993-10:2010), Acute Systemic Toxicity Testing (ISO 10993-11:2006), Sensitization (ISO 10993-10:2010); Bacterial Reverse Mutation (ISO 10993-3:2014)

8. Clinical Test Conclusion

No Clinical Test conducted.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device (K172761)	Remark
Product Code	EIH	EIH	SAME
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	SAME
Class	II	II	SAME
Indications for Use	The Unshaded Dental Zirconia and Pre-Shaded Dental Zirconia are intended for use with CAD/CAM technology to produce all ceramic dental restorations as prescribed by a dentist.	New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded) are Intended for use with CAD/CAM technology to produce all ceramic dental restorations (full contour crowns, bridges, inlays, and Veneers) as prescribed by a dentist.	SAME
Basic Design Characteristic	Disc	Blocks, Disc, and Rod	SAME
Materials	$ZrO_2+Y_2O_3+HfO_2+Al_2O_3$ Meet the requirements of ISO 6872	$ZrO_2+Y_2O_3+HfO_2+Al_2O_3$ Meet the requirements of ISO 6872	SAME
Processing	Sintering at temperature around 1500 ℃	Sintering at temperature around 1500 ℃	SAME
Dimension	Various	Various	SAME
Single Use	Yes	Yes	SAME
Color	None and Pre-shaded	None, and Pre-shaded (for pre-shaded series)	SAME
Sterile	Non-sterile	Non-sterile	SAME
Performance Test	Comply with ISO 6872	Comply with ISO 6872	SAME
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SAME
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SAME

The proposed device is highly similar to the predicate device in the terms of indication for use, materials processing, color, sterile etc.. The only differences between the proposed and predicate device are:

a. The subject device only has disc, while the predicate device has blocks, disc and rod. This difference does not raise any safety or efficacy concerns, because both proposed and predicate has the disc shapes, and the proposed device has no other shapes outside the scope of predicate device.

b. Both subject device and predicate device has various dimension. This difference does no raise an safety or efficacy concerns, because no matter what size will not affect the physical/mechanical and biocompatibility properties of the proposed product, both the subject and predicate device have similar physical/mechanical and biocompatibility properties that met the requirements of ISO 6872 and ISO 10993.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.