Qinhuangdao Silide Ceramic 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 CN

November.29.2018

Re: K181816
Trade/Device Name: Ceramic Denture Zirconia Ceramics Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: October 25, 2018
Received: October 31, 2018

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/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,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.29 11:08:50 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181816

Device Name
Ceramic Denture Zirconia Ceramics Block

Indications for Use *(Describe)*
The Ceramic Denture Zirconia Ceramics Block 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.

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1. Date of Preparation

   11/29/2018

2. Sponsor

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3. Submission Correspondent

Mr. Ray Wang

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4. Trade/Classification Name
   Trade Name of Subject device: Ceramic Denture Zirconia Ceramics Block
   Classification Name: Porcelain Powder for Clinical Use
   Common Name: Powder, Porcelain
   Classification: 2;
   Product Code: EIH;
   Regulation Number: 21 CFR 872.6660；
   Review Panel: Dental;

5. Identification of Predicate Device
   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.

6. Indication For Use
   The Ceramic Denture Zirconia Ceramics Block 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.

7. Device Description
   Trade Name of Subject device: Ceramic Denture Zirconia Ceramics Block

   The Ceramic Denture Zirconia Ceramics Block are 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 is composed of ZrO_2+Y_2O_3+HfO_2+Al_2O_3. The performance of the Ceramic Denture Zirconia Ceramics Block conforms to ISO 6872:2015 Dentistry: Ceramic Materials.

   The Ceramic Denture Zirconia Ceramics Block are offered in four (4) different product families of shapes and a multitude of different sizes and are capable of being machined into complex dental shapes using modern machining methods.

Family	Shapes & Sizes Available
KC-Cercon System	Blocks: 20 x 26.5 x25, 20 x 50 x 25, 20 x 60 x25, 20 x 65 x25, 25 x 43 x 16, 36 x 75 x 16

	(mm).
KZ-Zirkonzahn System	Discs: 95 x 10, 95 x 12, 95 x 14, 95 x 16, 95 x 18, 95 x 20, 95 x 22, 95 x 25, 98 x 10, 98 x 12, 98 x 14, 98 x 16, 98 x 18, 98 x 20, 98 x 22, 98 x 25,100 x 10, 100x12, 100 x14, 100 x16, 100 x 18, 100 x 20, 100 x 22, 100 x 25 (mm)
KA-Amann Girrbach System	U Shaped: 90 x 71 x 12, 90 x 71 x 14, 90 x 71 x 16, 90 x 71 x 18, 90 x 71 x 20, 90 x 71 x 22, 90 x 71 x 25 (mm)
KK-KAVA System	Blocks: 20 x 42 x16, 16x 42 x 16, 16 x 60 x 20 (mm) Rods: 16 x 16, 20 x20 (mm)

Accessories/Components: The blocks are only item in the final/sale package, no other accessories/components associated with the proposed device.

Device Composition

ZrO2	< 96 % wt
Y203	>4%
HfO2	>1%
Al203	<1%

The Ceramic Denture Zirconia Ceramics Block are derived from zirconia powder that has been processed via axial die pressing, and followed by isostatic pressing, to achieve various shapes of uniform density and distribution. The Ceramic Denture Zirconia Ceramics Block are non-shaded, no colorants or fillers included in proposed device. The Ceramic Denture Zirconia Ceramics Block are disposable device, and provided as non-sterile.

Physical and mechanical properties for Ceramic Denture Zirconia Ceramics Block are shown in following table and are similar in nature to the predicate device.

ZrO2	< 96 % wt
Y203	>4%
HfO2	>1%
Al203	<1%
Crystal Morphology	Tetragonal
Color	Non-shaded

Density (pre sintering)	2.8 - 3. 2 g/cm3
Density (post sintering)	≥ 6 g/cm3
Fracture Toughness (post sintering)	≥ 900 Mpa
Sintering temperature	1530 ºC
Porosity	≤ 0.1%

Machining of Ceramic Denture Zirconia Ceramics Blocks should be carried out by qualified and trained dental professionals using appropriate CAD/CAM equipment found in professional dental restoration labs. At the time of fabrication, all associated fabrication equipment should be properly calibrated and serviced according to the machine's operators manual. When designing crowns and bridges using Ceramic Denture Zirconia Ceramics Blocks, the following minimum dimensions must be maintained:

Minimum wall thickness for anteriors: 0.4 mm

Minimum wall thickness for posteriors: 0.6 mm

Minimum section of connectors for posteriors (for three unit bridges): 9 mm2

Upon completion of the CAD/CAM machining processes of the porous blanks, the dental device (i.e., crown or bridge) must be oven sintered to achieve its full density and strength to harden the ZrO2 as detailed below.

Post-Fabrication Sintering Instructions:

Firing Times & Temperatures:

RT to 300 degrees C: 1hr

300 to 1000 degrees C: 1hr

1000 to 1530 degrees C: 3hrs

1530 degrees C: 2 hrs

Cooling Cycle to 100 Degree C: 5 hours

Post-Sintering Instructions:

Upon completion of the sintering process, crowns and bridges can also be sandblasted with 110 micrometer corundum sand with 4 bar pressure for about 5 seconds. The crown is treated with porcelain before placed in the patient's mouth.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device (K181816)	Predicate Device (K172761)	Remark
Product Code	EIH	EIH	SE
Regulation No.	21 CFR 872.6660	21 CFR 872.6660	SE
Class	II	II	SE
Intended Use	The Ceramic Denture Zirconia Ceramics Block 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.	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.	SE
Shapes	Blocks, Disc, Rod, and U-shaped	Blocks, Disc, and Rod	Analysis 1
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	SE
Processing	Sintering at temperature around 1500 ℃	Sintering at temperature around 1500 ℃	SE
Dimension	KC-Cercon System, 20 x 26.5 x25, 20 x 50 x 25, 20 x 60 x25, 20 x 65 x25, 25 x 43 x 16, 36 x 75 x 16 (mm).	Various	Analysis 2
	KZ-Zirkon zahn System 95 x 10, 95 x 12, 95 x 14, 95 x 16, 95 x 18, 95 x 20, 95 x 22, 95 x 25, 98 x 10, 98 x 12, 98 x 14, 98 x 16, 98 x 18, 98 x 20, 98 x 22, 98 x 25,100 x 10, 100x12, 100 x14, 100 x16, 100 x 18, 100 x 20, 100 x 22, 100 x 25 (mm)		
	KA-Amann Girrbach System U Shaped: 90 x 71 x 12, 90 x 71 x 14, 90 x 71 x 16, 90 x 71 x 18, 90 x 71 x 20, 90 x 71 x 22, 90 x 71 x 25 (mm)		
	KK-KAVA System Blocks: 20 x 42 x16, 16x 42 x 16, 16 x 60 x 20 (mm) Rods: 16 x 16, 20 x20 (mm)		
Density	≥ 6 g/cm^3	N.A.	Analysis 3
Sintering	1530 ℃	1500 ℃	Analysis 4

Temperature			
Bending Strength	≥900 MPa	N.A.	Analysis 5
Solubility	≤100 ug/cm3	N.A.	Analysis 6
Single Use	Yes	Yes	SE
Color	Non-shaded	None, and Pre-shaded (for pre-shaded series)	SE
Sterile	Non-sterile	Non-sterile	SE
Performance Test	Comply with ISO 6872	Comply with ISO 6872	SE
	Appearance Test; Dimension Test Radioactivity Test Density Test Bend strength test Chemical Solubility test; Porosity test; Coefficient of linear expansion test Fracture toughness test; Material ingredients test;		
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

The proposed device is highly similar to the predicate device in terms of indications for use, design, material, processing and color. The proposed device is different from the predicate device in the following:

1) The subject device has blocks, disc, U-shaped and rod, while the predicate device only has blocks, disc and rod. This difference does not raise any safety or efficacy concerns for two reasons: First, the initial product shape does not matter because they are going to be milled into the final shape before patient use. Secondly, all device with different shapes share same materials and manufacturing process, so they have same performance in physical, mechanical and biocompability.
2) The subject device has different size used to predicate device. All proposed device sizes are going to be milled into the final shape before patient use, and all device sizes share same materials and manufacturing process, so they have same performance in physical, mechanical and biocompability.
3) The subject device has different Density to predicate device. Since this performance value of predicate device is not available in the predicate device's 510K summary, so we consider it as different. The density of proposed device is ≥ 6 g/cm3, which is same with lots of device has been cleared by FDA, such as K160367, K180252. Those devices all have similar indication for use and materials with proposed device.
4) The subject device has different Sintering Temperature to predicate device, 1530 vs. 1500. Both the subject and predicate device have similar physical/mechanical properties that meet the requirement of ISO 6872.

5) The subject device has different Bending Strength to predicate device. Since this performance value of predicate device is not available in the predicate device's 510K summary, so we consider it as different. The Bending Strength of proposed device is ≥900 MPa, which is meet the requirements of ISO6872.

6) The subject device has different Solubility to predicate device. Since this performance value of predicate device is not available in the predicate device's 510K summary, so we consider it as different. The Solubility mainly affected by the materials composition, and the proposed device has same materials composition with the predicate device, then they shall have similar solubility performance. And also the Solubility will mainly affects the physical and mechanical property of the dental blanks and both the subject and predicate device have similar physical/mechanical properties that met the requirements of ISO 6872.

9. 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.

10. Clinical Test Conclusion

No Clinical Test conducted.

11. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is Substantially Equivalent as the predicate device.