



Shanghai New Century Dental Materials Co., Ltd.
% Mr. Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

November 17, 2017

Re: K172761

Trade/Device Name: New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded)
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 13, 2017
Received: September 13, 2017

Dear Mr. Shen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 -S

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

Indications for Use

510(k) Number (if known)

K172761

Device Name

New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded)

Indications for Use (Describe)

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.

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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K172761: 510(k) Summary:

Submitter & Foreign Manufacture Identification

Name: Shanghai New Century Dental Materials Co., Ltd.
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Shanghai, China.
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Contact Person

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Manton Business and Technology Services
37 Winding Ridge, Oakland, New Jersey 07436
Telephone: 608-217-9358
Email: cyshen@aol.com

Date of Summary: November 8, 2017

Device Name:

Proprietary Name: New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded)

Common Name: Dental Zirconia Ceramics

Classification Name: Powder, Porcelain

Device Classification: II

Regulation Number: 21 CFR 872.6660

Panel: Dental

Product Code: EIH

Predicate Device Information:

K140070 Luxer Shaded Zirconia

Device Description:

New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded) are derived from Zirconia powder that has been processed into their final net shapes. These blanks are then further fabricated into all-ceramic restorations such as crowns, bridges, veneers, inlay/onlay. The zirconia powder is composed of $\text{ZrO}_2 + \text{Y}_2\text{O}_3 + \text{HfO}_2 + \text{Al}_2\text{O}_3$. The performance of the dental blanks conforms to ISO 6872: 2008, *Dentistry: Ceramic Materials*

The shading effects of New Century All-Ceramic Dental Zirconia Blocks (Pre-Shaded) are achieved by blending different zirconia powder material, all from the same supplier; have almost identical composition, differing only in the trace amount of inorganic pigments to achieve the shading effects in dental blanks. The performance of the pre-shaded dental zirconia blanks also conforms to ISO 6872, *Dentistry: Ceramic Materials*

Indications for Use:

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.

Summary of Non-Clinical Performance Testing:

Bench testing was performed per ISO 6872:2008 and using internal testing procedures (for presintered and sintered density) to ensure that the New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded) met the specifications. All tests were verified to meet acceptance criteria. A biocompatibility assessment was conducted in accordance with ISO 10993-1.

Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Subject Device	Predicate Device (K140070)
Indication for Use	<u>New Century All-Ceramic Dental Zirconia Blocks (Un-Shaded & Pre-Shaded)</u> 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.	Luxer Shaded Zirconia blanks are Intended for use with CAD/CAM technology to produce all ceramic dental restorations (full contour crowns and bridges) as prescribed by a dentist.
Basic Design	Blocks, disc, and rod	Blocks
Materials	Yttria stabilized Zirconia from TOSOH TZ Series of zirconia (white, yellow, pink, and gray)	Yttria stabilized Zirconia from TOSOH TZ Series of zirconia (white, yellow, pink, and gray)
Processing	Sintering at temperature around 1500 °C	Public information not available
Dimension	Various	Various
Single Use	Yes	Yes

Color	None, and Pre-shaded (for pre-shaded series)	Pre-shaded
Sterile	Non-sterile	Non-sterile

Our device is highly similar to the predicate device in terms of indications for use, design, material, and work flow to fabricate dental restorations. Our device is different from the predicate device in the following:

- (1) The subject device has blocks, disc, and rod, while the predicate device only has blocks. 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, the dental zirconia blanks are known to have multiple different shapes, including blocks, discs, and rods, such as described in K141724 by Liaoning Upcera Company Limited.
- (2) The sintering temperature is about 1500 °C for the subject device, while this information is not publicly available for the predicate device. This difference does not raise any safety or efficacy concerns as the sintering temperature mainly affects the physical and mechanical property of the dental blanks. Both the subject and predicate device have similar physical/mechanical properties that met the requirements of ISO 6872.
- (3) The subject has both non-shaded and pre-shaded blanks, while the predicate device has only the pre-shaded series. This difference does not raise any safety or efficacy concerns because there are many non-shaded zirconia blanks on the market, such as described in K141724 by Liaoning Upcera Company Limited.

Conclusion

In conclusion, based on the indications for use, technology and non-clinical performance testing, New Century All-Ceramic Dentistry Zirconia Blocks (Un-Shaded and Pre-Shaded) are substantially equivalent to K140070 Luxer Shaded Zirconia.