Crown Porcelain Dental Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd.
P.O. Box 120-119
Shanghai, 200120 Cn

April 24, 2018

Re: K180252
Trade/Device Name: Crown Dental Zirconia Blank & Crown 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 27, 2018
Received: March 7, 2018

Dear Diana Hong:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180252

Device Name

Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank

Indications for Use *(Describe)*

Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and 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.

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Tab #7 510(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: K180252

1. Date of Preparation: 02/24/2018

2. Sponsor Identification

Crown Porcelain Dental Technology Co., Ltd.
5F.-1, No.189, Sec.2, Keelung Rd., Xinyi Dist.,
Taipei City 110, Taiwan

Establishment Registration Number: Not yet registered for the Number

Contact Person: Chu Lien Fan
Position: General Manager
Tel: +886-2-2732-4911 ext.11
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Betty Xiao (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank
Common Name: Zirconia Blocks

Regulatory Information

Classification Name: Powder, Porcelain
Classification: 2
Product Code: EIH
Regulation Number: 872.6660
Review Panel: Dental

Intended Use Statement:

Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Device Description

Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank are available in discs shape, and in various specifications, which are combinations of height (10~25mm), color model (0M1/A1~A4/B1~B4/C1~C4/D2~D4) and transparency model (T41/T45/T49/TR).

5. Identification of Predicate Device(s)

510(k) Number: K160367
Product Name: Nissin Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Manufacturer: Nissin-Metec China Co., Ltd.

6. 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, including

- Performance Test per ISO 6872 Fourth Edition 2015-06-01, Dentistry - Ceramic Materials.
- Density Test
- Cytotoxicity per ISO 10993-5:2009;
- Intracutaneous Reactivity Test per ISO 10993-10:2010;
- Sensitization Test per ISO 10993-10:2010

- Acute Systematic Toxicity per ISO 10993-11:2006;
- Genotoxicity Tests per ISO 10993-3:2014.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	**Subject Device** **Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank**	**Predicate Device** **K160367**
Product Code	EIH	EIH
Regulation Number	872.6660	872.6660
Intended Use	Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.	Nissin Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers
Feature	Colored	Uncolored and Colored
Shape	Discs	Semic, Rods, Blocks and Discs
Type and Class per ISO 6872: 2015	Type II Class 5	Type II Class 5
Sterility	Non-sterile	Non-Sterile
Chemical Composition (Weight %)	ZrO_2 >99.0% Inorganic Pigment (Al_2O_3, SiO_2, Fe_2O_3, Er_2O_3) < 1%	ZrO_2 ≥99.0% Inorganic Pigment (Fe_2O_3, Er_2O_3) ≤ 1%
Crystal Morphology	Tetragonal	Tetragonal
Density	6.00g/cm^3	6.00g/cm^3
Sintering temperature	1500±50℃	1500±50℃
Performance	Comply with ISO 6872	Comply with ISO 6872
Contact Level	surface device with permanent contact (>30 days)	surface device with permanent contact (>30 days)

Biocompatibility	Tested for Cytotoxicity, irritation, sensitization, accurate systematic toxicity, genotoxicity, no adverse react identified.	Tested for Cytotoxicity, irritation, sensitization, accurate systematic toxicity, genotoxicity, no adverse react identified.

Subject device, Crown Dental Zirconia Blank & Crown Dental Zirconia Pre-Shaded Blank, is very similar to the predicate device, except for an additional Inorganic Pigment, the difference will not result in any new safety and effectiveness issue.

Substantially Equivalent (SE) Conclusion

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