DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Nissin-metec China Co., Ltd.
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shaghai, 200120 CN

July 27, 2016

Re: K160367
Trade/Device Name: Nissin Dental Zirconia Blank & 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 and ELL
Dated: February 4, 2016
Received: February 9, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA

Tina Kiang
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)*

Device Name
Nissin Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank

Indications for Use *(Describe)*

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.

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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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: _____

1. Date of Preparation: 06/23/2016

2. Sponsor Identification

Nissin-Metec China Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

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

Regulatory Information

Classification Name: Porcelain Powder for Clinical Use
Classification: 2
Product Code: EIH
Regulation Number: 872.6660
Review Panel: Dental

Intended Use Statement:

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.

Device Description

Nissin Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blanks are available in various specifications, which are combinations of different dimensions and shapes (Semics, Rods, Blocks and Discs). Furthermore, each specification is available in twenty two (22) color configurations.

5. Identification of Predicate Device(s)

510(k) Number: K141724
Product Name: Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank
Manufacturer: Liaoning Upcera 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: 2008, 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 10993-3:2003.

The results of the non-clinical tests are listed as following:

Table 1 Results of Non-clinical Tests

Item	Testing result
Radioactivity	$<5.0\times10^{-3}$Bq・g^{-1} Conforms to ISO 6872
Flexural strength	≥800MPa Conforms to ISO 6872
Linear thermal expansion coefficient	$(10.5\pm0.5)\times10^{-6}K^{-1}$ Conforms to ISO 6872
Chemical solubility	$< 100\mu g\cdot cm^{-2}$ Conforms to ISO 6872
Density	$6g/cm^3$
Cytotoxicity	The test article showed none Cytotoxicity.
Intracutaneous Reactivity Test	The mean score difference between the test sample (the extracts from 0.9% sodium chloride solution and cotton oil) and the corresponding vehicle blank is 0.00 and 0.42, respectively.
Sensitization Test	The test material showed no device of causing sensitization.
Systematic Toxicity	The test article showed no systematic toxicity and met the requirement of ISO 10993-11: 2006 standard.
Mouse Lymphoma Mutagenesis Assay	The results indicated that the extracts of test article did not cause a positive response in the non-activated and S9-activated systems and were concluded to be negative.
AMES	The test article is considered non-mutagenic in this assay.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics

ITEM	**Subject Device** **Nissin Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank**	**Predicate Device** **K141724**
Product Code	EIH	EIH
Regulation Number	872.6660	872.6660
Intended Use	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,	Upcera Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank are used for dental restorations using different CAD/CAM or manual milling machines. All blanks are

	facings, and veneers.	processed thought dental laboratories or by dental professionals.
Feature	Uncolored and Colored	Uncolored and Colored
Shape	Semic, Rods, Blocks and Dics	Rods, Blocks and Dics
Type and Class per ISO 6872	Type II Class 6	Type II Class 6
Sterility	Non-sterile	Non-Sterile
Chemical Composition (Weight %)	$ZrO_2 \geq 99.0\%$ Inorganic Pigment $(Fe_2O_3, Er_2O_3) \leq 1\%$	$ZrO_2 \geq 99.0\%$ Inorganic Pigment $(Fe_2O_3, Er_2O_3 Pr_2O_3) \leq 2\%$
Crystal Morphology	Tetragonal	Tetragonal
Density	$6.00 g/cm^3$	$6.00 g/cm^3$
Sintering temperature	$1500 \pm 50℃$	$>1500℃$
Radioactivity	$< 5.0 \times 10^{-3} Bq \cdot g^{-1}$	$< 1.0 Bq \cdot g^{-1}$
Flexural strength	$\geqslant 800MPa$	$\geqslant 800MPa$
Linear thermal expansion coefficient	$(10.5 \pm 0.5) \times 10^{-6} K^{-1}$	$(10.5 \pm 0.5) \times 10^{-6} K^{-1}$
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, genotoxicity, no adverse react identified.	Tested for Cytotoxicity, irritation, sensitization, genotoxicity, no adverse react identified.

Substantially Equivalent (SE) Conclusion

Subject device, Nissin Dental Zirconia Blank & Dental Zirconia Pre-Shaded Blank, is very similar to the predicate device, except for the different wording for intended use and an additional shape (Semic). For different wording for intended use, they share same intended use actually. Both of the proposed device and predicate device are intended for production of artificial teeth using CAD/CAM or manual milling machines. For the additional shape (Semic), the device has same compositions for each shape. The performance of this product is mainly affected by the compositions instead of its shape. Therefore, these differences will not effect equivalence.

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