September 23, 2022

Kuraray Noritake Dental Inc.
Yasujiro Ohara
Manager
Tokiwabashi Tower, 2-6-4, Otemachi
Chiyoda-ku, Tokyo 100-0004
JAPAN

Re: K220369
Trade/Device Name: Esthetic Colorant
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH,
Dated: August 24, 2022
Received: August 26, 2022

Dear Yasujiro Ohara:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220369

Device Name
Esthetic Colorant

Indications for Use *(Describe)*
Esthetic Colorant is used for coloring pre-sintered zirconia structures for the fabrication of all-ceramic restorations.

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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Date: March 8, 2022

510(k) Summary

K220369

1. 510(k) submitters information

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Yasujiro Ohara Manager Quality Assurance Department
4) Contact person in USA	Manabu Suzuki Director KURARAY AMERICA, INC. 32 Old Slip, 7th Floor, New York, NY 10005 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

2. Subject device identification

1) Trade / Proprietary name	Esthetic Colorant
2) Common Name	Coloring liquid for zirconia structures
3) Classification Number / Name	21 CFR 872.6660 / Porcelain Powder for Clinical Use
4) Class	II
5) Product code	EIH
6) Panel	Dental

3. Legally marketed predicate device

1) Company	Zirkonzahn srl
2) Device name	Zirkonzahn COLOUR LIQUID
3) Common Name	Liquid for Dental Zirconia Prosthesis
4) Classification Number / Name	21 CFR 872.6660 / Porcelain Powder for Clinical Use
5) Class	II
6) Product code	EIH
7) Panel	Dental
8) 510(k) Number	K190518

4. Device description

Esthetic Colorant, a colorant with a zirconia structure, is a dilute aqueous solution of transition metal salts and lanthanoid metal salts and enables appropriate color adjustment when combined with a pre-sintered zirconia structure such as KATANA Zirconia (K143439).

Esthetic Colorant colors the pre-sintered zirconia structure by applying it with a metal-free brush. The structure is then dried and then sintered at temperatures above 1400°C. Sintering welds the coloring components in Esthetic Colorant, making it possible to adjust the color shade of the zirconia structure.

Esthetic Colorant has 12 shades in bottle size (12 ml). In addition, Esthetic Colorant can only be used by professional technicians in the field of dentistry.

5. Indications for Use / Intended Use

Esthetic Colorant is used for coloring pre-sintered zirconia structures for the fabrication of all-ceramic restorations.

6. Performance data

Non-clinical testing was performed to evaluate the physical and chemical properties of the colored pre-sintered zirconia structures to demonstrate that the subject device of interest did not adversely affect the function of the zirconia structures. Since the product used for the evaluation is a dental zirconia structure, the physical and chemical properties were evaluated according to ISO 6872: 2015. As a result of the evaluation, the subject device does not have an adverse effect, so it is suitable for the purpose of use.

7. Performance data summary

7-1. Summary of physical properties to the product standard (ISO 6872:2015)

Product	Flexural strength	Test Result
KATANA Zirconia (HT)	Equal to or greater than 900MPa.	COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (B plus)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (BROWN)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (ORANGE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (BLUE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (GRAY)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (VIOLET)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (OPAQUE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (PINK)		COMPLIES

Product	Coefficient of thermal expansion	Test Result
KATANA Zirconia (HT)	The coefficient of thermal expansion of the ceramics shall not deviate by more than $0.5 \times 10^{-6} K^{-1}$ from the value stated by the manufacturer.	COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (B plus)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (BROWN)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (ORANGE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (BLUE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (GRAY)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (VIOLET)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (OPAQUE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (PINK)		COMPLIES

7-2. Summary of chemical properties to the product standard (ISO 6872:2015)

Product	Chemical solubility	Test Result
KATANA Zirconia (HT)	Less than to 100µg/cm^2.	COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (B plus)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (BROWN)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (ORANGE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (BLUE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (GRAY)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (VIOLET)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (OPAQUE)		COMPLIES
KATANA Zirconia (HT) Shaded with Esthetic Colorant (PINK)		COMPLIES

8. Substantial Equivalence Discussion

Properties and information	Subject device: Esthetic Colorant	Predicate device: (K190518) Zirkonzahn COLOUR LIQUID	Comparison comments
Company	Kuraray Noritake Dental Inc.	Zirkonzahn srl	—
Product code	EIH	EIH	Same
Regulation name (Regulation No.)	Porcelain powder for clinical use (872.6660)	Porcelain powder for clinical use (872.6660)	Same
Indications for use/ Intended use	Esthetic Colorant is used for coloring pre-sintered zirconia structures for the fabrication of all-ceramic restorations.	Zirkonzahn COLOUR LIQUID is used for coloring pre-sintered zirconia structures.	Similar
Technology	Aqueous solutions of transition and lanthanoid metal salts.	Aqueous solutions of transition and lanthanoid metal salts.	Similar
Chemical composition	A solvent consisting mostly of water. A solute consisting of transition and lanthanoid metal salts. Other chemical ingredients.	A solvent consisting mostly of water. A solute consisting of transition and lanthanoid metal salts.	Minor difference (Note 5-8-1.)
Operating principle	Brush zirconia ceramic structures with coloring liquid before sintering	Brush or immerse zirconia ceramic structures with coloring liquid before sintering	Similar
Type of packaging and volume	Bottle; 12 ml	Bottle; 20 ml, 50 ml, 100 ml	Similar
Shade	Various	Various	Similar
Storage conditions	Max: 30°C, 2 years	Max: 25°C, 5 years	Minor difference (Note 5-8-2.)
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility	Established (the worst case biocompatibility with ISO 10993-1:2018)	Established (the worst case biocompatibility with ISO 10993-1:2010).	Similar (Note 5-8-3.)

8-1. Discussion of chemical composition

The subject device and the predicate device are the same in that they are aqueous solutions of transition metal salts and lanthanoid metal salts. As the subject device contains other chemical ingredients, we evaluated the biocompatibility of the subject device in combination with 510(k) cleared dental zirconia and confirmed that these differences of chemical composition did not affect the biological safety of the subject device.

8-2. Discussion of storage conditions

In order to establish the storage conditions of the subject device, the test sample was accelerated and deteriorated and the requirements of ISO 6872:2015 was evaluated, and it was confirmed that there was no problem.

8-3. Established of biocompatibility

Biocompatibility was evaluated using the same ISO 10993-1 as the predicate device. Biocompatibility test was evaluated on the worst case model of the subject device as in the predicate device, and it was confirmed that the subject device satisfied biocompatibility.

9. Conclusion

The subject device and the predicate device are composed of similar chemical composition, and the difference does not matter. It was also confirmed that there was no problem with storage conditions and biocompatibility. From the above, it was judged that the two were substantially equivalent. In addition, from performance tests, the subject device serves its intended use.