May 29, 2025

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

Re: K250673
Trade/Device Name: CERABIEN MiLai
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH,
Dated: March 6, 2025
Received: March 6, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250673

Device Name

CERABIEN MiLai

Indications for Use *(Describe)*

For use in prosthetic dentistry to create an all-ceramic prosthesis.
- Ceramic for coverage of a zirconia substructure
- Ceramic for coverage of a lithium disilicate substructure
[CTE: 9.5-11.0×10-6/K (50-500°C)]

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K250673

510(k) Summary

Prepared on: 2025-03-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Kuraray Noritake Dental Inc.
Applicant Address	Tokiwabashi Tower, 2-6-4, Otemachi Chiyoda-ku Tokyo 100-0004 Japan
Applicant Contact Telephone	+81-3-6701-1736
Applicant Contact	Mr. Yasujiro Ohara
Applicant Contact Email	Knd.Regist@kuraray.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CERABIEN MiLai
Common Name	Porcelain powder for clinical use
Classification Name	Powder, Porcelain
Regulation Number	872.6660
Product Code(s)	EIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213147	CERABIEN MiLai	EIH
K043462	CZR PRESS LF	EIH
K170834	CERABIEN ZR	EIH

Device Description Summary

21 CFR 807.92(a)(4)

CERABIEN MiLai is a specific type of porcelain for dental restorations. The system consists of Powder, Paste and Liquids for powder/paste, to be applied utilizing layering technique and baked onto a ceramic frame of zirconia (ZrO_2) or different lithium disilicate glasses ($Li_2O_5Si_2$)

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

For use in prosthetic dentistry to create an all-ceramic prosthesis.
- Ceramic for coverage of a zirconia substructure
- Ceramic for coverage of a lithium disilicate substructure
[CTE: 9.5-11.0×10-6/K (50-500°C)]

Indications for Use Comparison

21 CFR 807.92(a)(5)

Although the coefficient of thermal expansion (CTE) of the subject device and the primary predicate device is slightly different, both the subject device and the primary predicate device are designed to be applied utilizing layering technique and baked onto a ceramic frame of zirconia (ZrO2) or lithium disilicate glass (Li2O5Si2). Moreover, except for the coefficient of thermal expansion (CTE), the Indications for use of both the subject device and the primary predicate device is the same. Regarding the range of the coefficient of thermal expansion (CTE), we evaluated the thermal shocking testing with different lithium disilicate substrates, which the CTE ranged from 9.5×10-6/K to 11.0×10-6/K. As a result, it was confirmed that the subject device met the requirement of thermal shocking testing according to ISO 9693: 2019, and the performance test result of subject device could support the specific indications of the subject device in addition of different lithium disilicate substrates, which the CTE ranged from 9.5×10-6/K to 11.0×10-6/K.
Therefore, it was concluded that the Indications for use of the subject device is substantially equivalent to that of the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The performance tests are conducted to confirm the conformity of the standards.
And it was also evaluated that physical properties of the subject device are substantially equivalent to those of the primary predicate device.
The results indicated that the subject device met the requirements of ISO 6872: 2015 and ISO 9693: 2019 as well as the primary predicate device, which is important for this submission since ISO 6872 is a recognized consensus standard for the Product Code "EIH." and ISO 9693 is an FDA recognized standard for compatibility testing for ceramic-ceramic systems.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Physical and mechanical tests were conducted according to ISO 6872: 2015 and ISO 9693: 2019. As a result, this test confirms that the subject device meets the requirements of ISO 6872: 2015 and ISO 9693: 2019 as well as the primary predicate device, which is important for this submission since ISO 6872 is a recognized consensus standard for the Product Code "EIH." and ISO 9693 is an FDA recognized standard for compatibility testing for ceramic-ceramic systems.
Moreover, to confirm the subject device could be used on different lithium disilicate substrates, which the CTE ranged from 9.5×10-6/K to 11.0×10-6/K, the thermal shocking testing was conducted according to ISO 9693: 2019. As a result, the subject device meets the requirement of thermal shocking testing according to ISO 9693: 2019, and the performance test result of subject device could support the specific indications of the subject device in addition of different lithium disilicate substrates, which the CTE ranged from 9.5×10-6/K to 11.0×10-6/K.

FDA recognized consensus standards
ISO 6872: 2015; FR Recognition Number 4-251
ISO 9693: 2019; FR Recognition Number 4-263

Not Applicable

In conclusion, the nonclinical tests results indicate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.