

K250673 CERABIEN MiLaiMay 29, 2025
84 days to decisionK250673 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k250673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Mar 6, 2025
Decision date	May 29, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kuraray Noritake Dental, Inc.
Location	New York, NY, US
Contact	Yasujiro Ohara
510(k) history	32 submissions · 32 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250673/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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