

K131534 KATANA ZIRCONIAOct 11, 2013
135 days to decisionK131534 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k131534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	May 29, 2013
Decision date	Oct 11, 2013
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026