

K150703 CLEARFIL CERAMIC PRIMER PLUS, CLEARFIL CERAMIC PRIMER PLUS (Trial)Aug 13, 2015
148 days to decisionK150703 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k150703/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Mar 18, 2015
Decision date	Aug 13, 2015
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150703/> 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 4, 2026