

**K061322 PORCELAIN PRIMER**Jun 2, 2006  
22 days to decisionK061322 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k061322/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 11, 2006
Decision date	Jun 2, 2006
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>J. Morita USA, Inc.</b>
Location	Irvine, CA, US
Contact	HOWARD ROWE
510(k) history	52 submissions · 52 cleared · 1988-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061322/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026