

**K112574 PRIME-DENT DUAL CURE COMPOSITE LUTING  
CEMENT**Jan 23, 2012  
139 days to decisionK112574 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k112574/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Sep 6, 2011
Decision date	Jan 23, 2012
Days to decision	139 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Prime Dental Manufacturing, Inc.</b>
Location	Chicago, IL, US
Contact	JAVIER ALVAREZ
510(k) history	9 submissions · 9 cleared · 2000-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112574/> 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 15, 2026