

K896340 BIOMER(R) F COMPOSITE LUTING CEMENTMay 15, 1990
193 days to decisionK896340 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k896340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Nov 3, 1989
Decision date	May 15, 1990
Days to decision	193 days
Third-party review	No

APPLICANT

Company	Dentsply Intl.
Location	Walker, MI, US
Contact	JEFFERY LEHN
510(k) history	279 submissions · 279 cleared · 1976-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k896340/>, 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 May 19, 2026