

K991711 BISTITE II SCJul 7, 1999
49 days to decisionK991711 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k991711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	May 19, 1999
Decision date	Jul 7, 1999
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tokuyama America, Inc.
Location	Washington, DC, US
Contact	DANIEL J MANELLI
510(k) history	22 submissions · 22 cleared · 1990-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991711/> 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 July 2, 2026