

**K011685 BISTITE II DC**Jul 31, 2001  
61 days to decisionK011685 · Product code: **EMA** · Dental  
Source: <https://www.510kdatabase.net/k011685/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	May 31, 2001
Decision date	Jul 31, 2001
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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