FDA 510(k) Premarket Notification

K991711 BISTITE II SC

CLEARED

Jul 7, 1999
49 days to decision

K991711 · 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