

K980054 PALFIQUE ESTELITEApr 27, 1998
111 days to decisionK980054 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k980054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 6, 1998
Decision date	Apr 27, 1998
Days to decision	111 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

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