

K982164 ESTENIAAug 10, 1998
52 days to decisionK982164 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k982164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jun 19, 1998
Decision date	Aug 10, 1998
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kuraray America, Inc.
Location	New York, NY, US
Contact	KOJI FUJITA
510(k) history	11 submissions · 11 cleared · 1997-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982164/> 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 June 16, 2026