

**K012707 ESTENIA**Sep 13, 2001  
30 days to decisionK012707 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k012707/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 14, 2001
Decision date	Sep 13, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kuraray Medical, Inc.</b>
Location	New York, NY, US
Contact	MASAYA SASAKI
510(k) history	42 submissions · 42 cleared · 2001-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012707/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 15, 2026