

**K042929 ESTENIA C&B**Dec 6, 2004  
45 days to decisionK042929 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k042929/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Oct 22, 2004
Decision date	Dec 6, 2004
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kuraray Medical Kurashiki Plant</b>
Location	New York, NY, US
Contact	KOJI NISHIDA
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042929/> 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 July 1, 2026