

**K003034 COLTENE AURA COMPOMER RESTORATIVE SYSTEM**Nov 30, 2000  
63 days to decisionK003034 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k003034/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 28, 2000
Decision date	Nov 30, 2000
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Coltene/Whaledent, Inc.</b>
Location	New York, NY, US
Contact	H. J VOGELSTEIN
Website	<a href="https://ap.coltene.com/">https://ap.coltene.com/</a>
510(k) history	21 submissions · 21 cleared · 1991-2007

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003034/>; 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 26, 2026