

**K010250 TETRIC CERAM HB**Feb 28, 2001  
33 days to decisionK010250 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k010250/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 26, 2001
Decision date	Feb 28, 2001
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ivoclar North America, Inc.</b>
Location	Amherst, NY, US
Contact	ANDY GULATI
510(k) history	131 submissions · 131 cleared · 1989-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010250/> 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 2, 2026