

**K901918 HELIOTINT**Jun 26, 1990  
61 days to decisionK901918 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k901918/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 26, 1990
Decision date	Jun 26, 1990
Days to decision	61 days
Third-party review	No

**APPLICANT**

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Company	<b>Ivoclar North America, Inc.</b>
Location	Amherst, NY, US
Contact	L SEVERANCE, DDS
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/k901918/>; 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