

**K010219 CHALLENGER DIRECT COMPOSITE**Feb 21, 2001  
28 days to decisionK010219 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k010219/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 24, 2001
Decision date	Feb 21, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>International Dental Research</b>
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	1 submissions · 1 cleared · 2001-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010219/> 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