

**K001518 GRADIA**Jul 5, 2000  
50 days to decisionK001518 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k001518/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 16, 2000
Decision date	Jul 5, 2000
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>GC America, Inc.</b>
Location	Alsip, IL, US
Contact	TERRY L JORITZ
510(k) history	126 submissions · 126 cleared · 1993-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001518/> 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 28, 2026