

K984365 GC UNIFAST TRADFeb 25, 1999
80 days to decisionK984365 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k984365/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI) |
| Date received | Dec 7, 1998 |
| Decision date | Feb 25, 1999 |
| Days to decision | 80 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984365/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026