

K090747 MI FLOW (GCUC-450)Jun 10, 2009
82 days to decisionK090747 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k090747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Mar 20, 2009
Decision date	Jun 10, 2009
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	GC America, Inc.
Location	Alsip, IL, US
Contact	MARK HEISS
510(k) history	126 submissions · 126 cleared · 1993-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090747/> 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 22, 2026