

**K861546 REPLICA-F VISIBLE LIGHT-CURED ANT/POST DEN
COM KIT**May 21, 1986
26 days to decisionK861546 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k861546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Apr 25, 1986
Decision date	May 21, 1986
Days to decision	26 days
Third-party review	No

APPLICANT

Company	Macrochem Corp.
Location	Woburn, MA, US
Contact	JAMES R MARSHALL
510(k) history	5 submissions · 4 cleared · 1986-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861546/> 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 July 5, 2026