

K890494 FLUOREVER PIT AND FISSURE SEALANT OR FLUOREVER PFS

Mar 29, 1989
57 days to decision

K890494 · Product code: **EBC** · Dental
Source: <https://www.510kdatabase.net/k890494/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Jan 31, 1989
Decision date	Mar 29, 1989
Days to decision	57 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k890494/>; 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