

**K941532 BIOCALEX 6/9**Aug 2, 1994  
125 days to decisionK941532 · Product code: **EJK** · DentalSource: <https://www.510kdatabase.net/k941532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liner, Cavity, Calcium Hydroxide (EJK)
Date received	Mar 30, 1994
Decision date	Aug 2, 1994
Days to decision	125 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bio-Probe, Inc.</b>
Location	Orlando, FL, US
Contact	SAM ZIFF
510(k) history	2 submissions · 2 cleared · 1993-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941532/> 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 July 3, 2026