FDA 510(k) Premarket Notification

K941532 BIOCALEX 6/9

CLEARED

Aug 2, 1994
125 days to decision

K941532 · Product code: **EJK** · Dental
Source: https://www.510kdatabase.net/k941532/

SUBMISSION DETAILS

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

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