FDA 510(k) Premarket Notification

K943372 CALCIUM HYDROXIDE PASTE

CLEARED

Sep 19, 1994
68 days to decision

K943372 · Product code: **EJK** · Dental
Source: https://www.510kdatabase.net/k943372/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liner, Cavity, Calcium Hydroxide (EJK)
Date received	Jul 13, 1994
Decision date	Sep 19, 1994
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ultradent Products, Inc.**
Location	Salt Lake City, UT, US
Contact	L.M. CHATWIN
Website	https://www.ultradent.com
510(k) history	103 submissions · 103 cleared · 1992-2026