FDA 510(k) Premarket Notification

K964809 SPETEMP EF

CLEARED

Jan 2, 1997
34 days to decision

K964809 · Product code: **EMA** · Dental
Source: https://www.510kdatabase.net/k964809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Nov 29, 1996
Decision date	Jan 2, 1997
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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