FDA 510(k) Premarket Notification

K950860 PERMALUTE

CLEARED

Mar 23, 1995
24 days to decision

K950860 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k950860/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Feb 27, 1995
Decision date	Mar 23, 1995
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

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