FDA 510(k) Premarket Notification

K983668 MODIFICATION OF PQ1

CLEARED

Nov 30, 1998
42 days to decision

K983668 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k983668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Oct 19, 1998
Decision date	Nov 30, 1998
Days to decision	42 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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