FDA 510(k) Premarket Notification

K974283 PQ 1

CLEARED

Jan 29, 1998
76 days to decision

K974283 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k974283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Nov 14, 1997
Decision date	Jan 29, 1998
Days to decision	76 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