FDA 510(k) Premarket Notification

K131049 ZRP

CLEARED

Aug 27, 2013
134 days to decision

K131049 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k131049/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Apr 15, 2013
Decision date	Aug 27, 2013
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Apex Dental Materials, Inc.**
Location	Schaumburg, IL, US
Contact	CHRIS KULTON
510(k) history	15 submissions · 15 cleared · 2001-2019