FDA 510(k) Premarket Notification

K182162 OptiBond eXTRa Universal

CLEARED

Nov 7, 2018
89 days to decision

K182162 · Product code: **KLE** · Dental
Source: https://www.510kdatabase.net/k182162/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	Aug 10, 2018
Decision date	Nov 7, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kerr Corporation**
Location	Newport Beach, CA, US
Contact	Mohammad Saad Ansari
510(k) history	32 submissions · 32 cleared · 2006-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182162/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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