FDA 510(k) Premarket Notification

K072622 STANDOUT 2

CLEARED

Dec 4, 2007
78 days to decision

K072622 · Product code: **ELW** · Dental
Source: https://www.510kdatabase.net/k072622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Sep 17, 2007
Decision date	Dec 4, 2007
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kerr Corp.**
Location	Orange, CA, US
Contact	Wendy Garman
510(k) history	9 submissions · 9 cleared · 2000-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k072622/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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