FDA 510(k) Premarket Notification

K172164 PROPEL Device

CLEARED

Jan 17, 2018
183 days to decision

K172164 · Product code: **DZJ** · Dental
Source: https://www.510kdatabase.net/k172164/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Driver, Wire, And Bone Drill, Manual (DZJ)
Date received	Jul 18, 2017
Decision date	Jan 17, 2018
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Propel Orthodontics, LLC**
Location	Milpitas, CA, US
Contact	Bryce Way
510(k) history	3 submissions · 3 cleared · 2015-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k172164/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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