

K181112 Orchestra 3DNov 26, 2018
213 days to decisionK181112 · Product code: **PNN** · Dental
Source: <https://www.510kdatabase.net/k181112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Apr 27, 2018
Decision date	Nov 26, 2018
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orchestra 3D
Location	Rialto, CA, US
Contact	Todd Ehrler
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Jcq Consulting
Contact	Bill Jacqmein

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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