

K212772 Precision AlignJan 15, 2022
137 days to decisionK212772 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k212772/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Aug 31, 2021
Decision date	Jan 15, 2022
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Align, LLC
Location	Fort Lauderdale, FL, US
Contact	Chris Freeman
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Evo820, LLC
Contact	Na Zhang

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

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