

**K232564 Align Studio**Mar 12, 2024  
201 days to decisionK232564 · Product code: **PNN** · Dental  
Source: <https://www.510kdatabase.net/k232564/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Aug 24, 2023
Decision date	Mar 12, 2024
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Laon Medi, Inc.</b>
Location	Seongnam-Si, KR
Contact	Mina Yun
510(k) history	2 submissions · 2 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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