

**K222308 AI Smile Aligner**Dec 20, 2022  
141 days to decisionK222308 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k222308/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Aug 1, 2022
Decision date	Dec 20, 2022
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanjing Jiahe Dental Technology Co., Ltd.</b>
Location	Nanjing, CN
Contact	Charles Shen
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Manton Business and Technology Services</b>
Contact	Charles Shen

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

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