

K251415 Additively Manufactured Aligner ResinAug 27, 2025
112 days to decisionK251415 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k251415/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 7, 2025
Decision date	Aug 27, 2025
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aidite (Qinhuangdao) Technology Co., Ltd.
Location	Qinhuangdao, CN
Contact	Zhanfu Ye
510(k) history	16 submissions · 16 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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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