

K223454 Custom-made Invisible AlignersApr 17, 2023
152 days to decisionK223454 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k223454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Nov 16, 2022
Decision date	Apr 17, 2023
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Yinchili Medical Technology Co., Ltd.
Location	Jiaxing, CN
Contact	Xinyan Zhang
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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

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