FDA 510(k) Premarket Notification

K251454 Clear Aligner (SCF-3348)

CLEARED

Jan 7, 2026
240 days to decision

K251454 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k251454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 12, 2025
Decision date	Jan 7, 2026
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beame Medical Technology (Shenzhen) Limited**
Location	Shenzhen, CN
Contact	Yajuan Ou
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Riley Chen

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