FDA 510(k) Premarket Notification

K223517 Clear Aligner

CLEARED

Jun 13, 2023
202 days to decision

K223517 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k223517/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Nov 23, 2022
Decision date	Jun 13, 2023
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wuxi EA Medical Instruments Technologies Limited.**
Location	Wuxi, CN
Contact	Jessica Luo
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Breanne Butler

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