FDA 510(k) Premarket Notification

K210373 Clear Aligners

CLEARED

Aug 27, 2021
200 days to decision

K210373 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k210373/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Feb 8, 2021
Decision date	Aug 27, 2021
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Yinuo Dental Technology Co.Ltd**
Location	Shenzhen, CN
Contact	Mo Yuyum
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Gamma Zhang

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