FDA 510(k) Premarket Notification

K220835 Arkligners

CLEARED

Aug 12, 2022
143 days to decision

K220835 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k220835/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Mar 22, 2022
Decision date	Aug 12, 2022
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arklign Laboratories**
Location	San Jose, CA, US
Contact	Rex Ho
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

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