FDA 510(k) Premarket Notification

K221537 Nightwear Aligners

CLEARED

Apr 5, 2023
313 days to decision

K221537 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k221537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 27, 2022
Decision date	Apr 5, 2023
Days to decision	313 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Smylio, Inc.**
Location	Fremont, CA, US
Contact	Ren Menon
510(k) history	3 submissions · 3 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Jennifer Day

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