FDA 510(k) Premarket Notification

K260788 Smylio Aligners

CLEARED

May 8, 2026
59 days to decision

K260788 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k260788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Mar 10, 2026
Decision date	May 8, 2026
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Smylio, Inc.**
Location	Fremont, CA, US
Contact	Ren Menon
510(k) history	4 submissions · 4 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Kole Villescas

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