FDA 510(k) Premarket Notification

K242929 Fas Aligner System

CLEARED

Dec 20, 2024
87 days to decision

K242929 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k242929/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 24, 2024
Decision date	Dec 20, 2024
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xplora 3D Europe S.L**
Location	Madrid, ES
Contact	Esther Aznar
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Compliance4Devices**
Contact	Juan Tezak

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