

**K242929 Fas Aligner System**Dec 20, 2024  
87 days to decisionK242929 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k242929/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Compliance4Devices</b>
Contact	Juan Tezak

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

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