

K232653 Blue Sky Plan Software, Blue Sky Bio Aligner Z, and Blue Sky Bio Aligner Z FLXApr 3, 2024
216 days to decisionK232653 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k232653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Aug 31, 2023
Decision date	Apr 3, 2024
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Blue Sky Bio, LLC
Location	Grayslake, IL, US
Contact	Albert Zickmann
510(k) history	16 submissions · 16 cleared · 2005-2024

REGULATORY CONSULTANT

Consulting firm	Trisler Consulting, Dba
Contact	Patsy J Trisler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026