

**K221845 Blue Sky Bio Aligner G & Blue Sky Plan S/W for Blue Sky Bio Aligner G**

Feb 24, 2023  
245 days to decision

K221845 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k221845/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Aligner, Sequential (NXC)
Date received	Jun 24, 2022
Decision date	Feb 24, 2023
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)  
 Device record: <https://www.510kdatabase.net/k221845/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).  
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