

K180107 Blue Sky Bio AlignerFeb 9, 2018
24 days to decisionK180107 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k180107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jan 16, 2018
Decision date	Feb 9, 2018
Days to decision	24 days
Third-party review	Yes
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

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