

**K200005 Concinnity Aligners**Nov 9, 2020  
312 days to decisionK200005 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k200005/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jan 2, 2020
Decision date	Nov 9, 2020
Days to decision	312 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Drake Precision Dental Laboratory, Inc.</b>
Location	Charlotte, NC, US
Contact	Robert Savage
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bdra Consulting, LLC</b>
Contact	Srinagesh Koushik

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200005/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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