

**K182388 Krystal Klear Aligners**Dec 19, 2019  
471 days to decisionK182388 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k182388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 4, 2018
Decision date	Dec 19, 2019
Days to decision	471 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shatkin F.I.R.S.T., LLC</b>
Location	Amherst, NY, US
Contact	Kimberly Wiesmore
510(k) history	1 submissions · 1 cleared · 2019-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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