

**K192338 NEOLab Clear Aligners**Mar 12, 2020  
197 days to decisionK192338 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k192338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Aug 28, 2019
Decision date	Mar 12, 2020
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New England Ortho Lab, Inc.</b>
Location	Andover, MA, US
Contact	Olivia Channon
510(k) history	2 submissions · 2 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192338/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026