

K191308 U-AlignerApr 23, 2020
345 days to decisionK191308 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k191308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 14, 2019
Decision date	Apr 23, 2020
Days to decision	345 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Universal Orthodontic Laboratory, Inc.
Location	Norwalk, CA, US
Contact	Jiahe Li
510(k) history	1 submissions · 1 cleared · 2020-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191308/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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