

K211510 uLab Systems Dental Aligner KitFeb 24, 2022
286 days to decisionK211510 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k211510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 14, 2021
Decision date	Feb 24, 2022
Days to decision	286 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ulab Systems, Inc.
Location	Menlo Park, CA, US
Contact	Amir Albolfathi
510(k) history	4 submissions · 4 cleared · 2018-2022

REGULATORY CONSULTANT

Consulting firm	Sylvia Erickson Consulting
Contact	Sylvia Erickson

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

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