

K201104 AsoAlignerFeb 26, 2021
308 days to decisionK201104 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k201104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Apr 24, 2020
Decision date	Feb 26, 2021
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aso International Manila, Inc.
Location	Cavite, PH
Contact	Hikomichi Takahashi
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Giselle Zhang

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

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