FDA 510(k) Premarket Notification

K210540 Ohlendorf Clear Aligner

CLEARED

May 19, 2021
84 days to decision

K210540 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k210540/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Feb 24, 2021
Decision date	May 19, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ohlendorf Appliance Laboratory**
Location	St. Louis, MO, US
Contact	Kevin Ohlendorf
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Trisler Consulting**
Contact	Patsy J. Trisler

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

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Device record: https://www.510kdatabase.net/k210540/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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