FDA 510(k) Premarket Notification

K221097 SmileSeries

CLEARED

Jul 14, 2022
91 days to decision

K221097 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k221097/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Apr 14, 2022
Decision date	Jul 14, 2022
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ordont Orthodontic Laboratories, Inc.**
Location	Fenton, MO, US
Contact	Paul Rudzicka
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Trisler Consulting, Dba**
Contact	Patsy J Trisler

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