FDA 510(k) Premarket Notification

K213297 Redline

CLEARED

Feb 9, 2022
131 days to decision

K213297 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k213297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Oct 1, 2021
Decision date	Feb 9, 2022
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Johns Dental Laboratories**
Location	Terre Haute, IN, US
Contact	Marni Buis
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Evo820, LLC**
Contact	Na Zhang

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