FDA 510(k) Premarket Notification

K191823 Clear-Aligners

K191823 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k191823/

CLEARED

Dec 20, 2019
165 days to decision

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jul 8, 2019
Decision date	Dec 20, 2019
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cdb Corporation**
Location	Leland, NC, US
Contact	Leah M. Lehman
510(k) history	6 submissions · 6 cleared · 2008-2022

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k191823/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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