FDA 510(k) Premarket Notification

K190003 Vivid Aligners

CLEARED

Nov 6, 2019
308 days to decision

K190003 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k190003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jan 2, 2019
Decision date	Nov 6, 2019
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Orthodent Laboratory, Inc.**
Location	Buffalo, NY, US
Contact	Michael Wright
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Compliance Systems International, LLC**
Contact	Robert O. Dean

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