FDA 510(k) Premarket Notification

K202792 BRIUS Clear Aligners

CLEARED

Jan 22, 2021
122 days to decision

K202792 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k202792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 22, 2020
Decision date	Jan 22, 2021
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Brius Technologies, Inc.**
Location	Carrollton, TX, US
Contact	Kate Garrett
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Medavice, Inc.**
Contact	Jennifer Day

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