FDA 510(k) Premarket Notification

K191838 Clearform Aligners

CLEARED

Mar 20, 2020
255 days to decision

K191838 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k191838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jul 9, 2019
Decision date	Mar 20, 2020
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Motor City Lab Works**
Location	Birmingham, MI, US
Contact	Christina Groth
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Aclivi, LLC**
Contact	Chris Brown

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