FDA 510(k) Premarket Notification

K190948 Magic Clear Aligners

CLEARED

May 9, 2019
28 days to decision

K190948 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k190948/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Apr 11, 2019
Decision date	May 9, 2019
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Voodoo Manufacturing, Inc.**
Location	Brooklyn, NY, US
Contact	Max Friefeld
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	MARK JOB

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