FDA 510(k) Premarket Notification

K192767 Clear Aligner

CLEARED

Jan 8, 2020
100 days to decision

K192767 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k192767/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 30, 2019
Decision date	Jan 8, 2020
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Royal Dental Lab**
Location	Shenzhen, CN
Contact	Mo Yuyun
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Becky Chen

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