FDA 510(k) Premarket Notification

K220726 K Clear

CLEARED

Mar 16, 2022
2 days to decision

K220726 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k220726/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Mar 14, 2022
Decision date	Mar 16, 2022
Days to decision	2 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Kline Europe GmbH**
Location	Dusseldorf, DE
Contact	Sherif Kandil
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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