FDA 510(k) Premarket Notification

K222764 LightForce Orthodontic System

CLEARED

Sep 14, 2022
1 days to decision

K222764 · Product code: **NJM** · Dental
Source: https://www.510kdatabase.net/k222764/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Sep 13, 2022
Decision date	Sep 14, 2022
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lightforce Orthodontics**
Location	Cambridge, MA, US
Contact	Kelsey Fafara
510(k) history	3 submissions · 3 cleared · 2020-2023

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