FDA 510(k) Premarket Notification

K211740 DualX

CLEARED

Sep 29, 2021
114 days to decision

K211740 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k211740/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jun 7, 2021
Decision date	Sep 29, 2021
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Amplify Surgical, Inc.**
Location	Laguna Hills, CA, US
Contact	Andy Choi
510(k) history	3 submissions · 3 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Meredith May

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