FDA 510(k) Premarket Notification

K222203 DualXSLIM(R) T/PLIF

CLEARED

Oct 18, 2022
85 days to decision

K222203 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k222203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jul 25, 2022
Decision date	Oct 18, 2022
Days to decision	85 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	Erickson Nathan
510(k) history	3 submissions · 3 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	**Empirical Technologies**
Contact	Nathan Wright

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222203/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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