FDA 510(k) Premarket Notification

K192434 DualX Lumbar Intervertebral Body Fusion Device

CLEARED

Oct 15, 2019
40 days to decision

K192434 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k192434/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 5, 2019
Decision date	Oct 15, 2019
Days to decision	40 days
Third-party review	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