

K192434 DualX Lumbar Intervertebral Body Fusion DeviceOct 15, 2019
40 days to decisionK192434 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192434/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026