

K162693 VertebraLINK Fusion PlatformMar 29, 2017
183 days to decisionK162693 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k162693/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 27, 2016
Decision date	Mar 29, 2017
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Facetlink Dbal Linkspine
Location	Rockaway, NJ, US
Contact	MASSIMO CALAFIORE
510(k) history	2 submissions · 2 cleared · 2016-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162693/> 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 16, 2026