

K161438 Genesys Spine Apache® Anterior Lumbar Interbody Fusion SystemNov 8, 2016
168 days to decisionK161438 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k161438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	May 24, 2016
Decision date	Nov 8, 2016
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genesys Spine
Location	Austin, TX, US
Contact	BRIAN BERGERON
510(k) history	31 submissions · 31 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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