

K182987 Genesys Spine 3DP Lumbar Interbody SystemDec 12, 2019
409 days to decisionK182987 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k182987/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Oct 29, 2018
Decision date	Dec 12, 2019
Days to decision	409 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genesys Spine
Location	Austin, TX, US
Contact	William W. Sowers
510(k) history	31 submissions · 31 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182987/> 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 15, 2026