

K180056 Genesys Spine AIS-C Cervical Anchored Interbody System

Mar 28, 2018
79 days to decisionK180056 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k180056/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jan 8, 2018
Decision date	Mar 28, 2018
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genesys Spine
Location	Austin, TX, US
Contact	Benjamin V. Keller
510(k) history	31 submissions · 31 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180056/> 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