

K242483 Genesys Spine AIS-C II Cervical Interbody Fusion SystemFeb 7, 2025
170 days to decisionK242483 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k242483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Aug 21, 2024
Decision date	Feb 7, 2025
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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