

K191489 Genesys Spine 3DP Cervical Interbody SystemJan 8, 2020
218 days to decisionK191489 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k191489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Jun 4, 2019
Decision date	Jan 8, 2020
Days to decision	218 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

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