

K130317 GENESYS SPINE APACHE IBFD STAR CERVICAL SYSTEM

Dec 11, 2013
306 days to decision

K130317 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k130317/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Feb 8, 2013
Decision date	Dec 11, 2013
Days to decision	306 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

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Device record: <https://www.510kdatabase.net/k130317/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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