

**K191748 Genesys Spine Sacroiliac Joint Fusion System**Sep 26, 2019  
87 days to decisionK191748 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k191748/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jul 1, 2019
Decision date	Sep 26, 2019
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191748/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 15, 2026