

**K212755 SIGNUS SACRONAIL® Transsacral Stabilization System**Mar 10, 2022  
191 days to decisionK212755 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k212755/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 31, 2021
Decision date	Mar 10, 2022
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Signus Medizintechnik GmbH</b>
Location	Minneapolis, MN, US
Contact	Holger Noss
510(k) history	23 submissions · 22 cleared · 1999-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kapstone Medical, LLC</b>
Contact	Carolyn Guthrie

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212755/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026