

**K221050 ZESPIN SI Joint Fusion System, Paeon Posterior Cervical Fixation System, Paeon Anterior Cervical Plate System, Spinema Lumbar Plate System**Jun 30, 2022  
80 days to decisionK221050 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k221050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Apr 11, 2022
Decision date	Jun 30, 2022
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aegis Spine, Inc.</b>
Location	Englewood, CO, US
Contact	Kihyang Kim
510(k) history	5 submissions · 5 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221050/> 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 26, 2026