

**K243838 NEXXT MATRIXX® SI System**Mar 14, 2025  
91 days to decisionK243838 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k243838/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 13, 2024
Decision date	Mar 14, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nexxt Spine</b>
Location	Noblesville, IN, US
Contact	Andy Elsbury
Website	<a href="https://nexxtspine.com">https://nexxtspine.com</a>
510(k) history	2 submissions · 2 cleared · 2024-2025

Nexxt Spine designs and manufactures spinal implants and instruments at its state-of-the-art facility in Noblesville, Indiana. The company specializes in 3D printed titanium interbodies, plating systems, pedicle screw systems, and related surgical instruments for spinal procedures. Since 2009, Nexxt Spine has maintained in-house manufacturing of 100% of implants and 95% of instruments. Nexxt Spine has received FDA 510(k) clearances from total submissions, with all submissions focused on Orthopedic devices. The company's regulatory activity spans 2024 to 2025, with the mos...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Technologies</b>
Contact	Hannah Taggart

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k243838/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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