

**K221047 SILO TFX MIS Sacroiliac Joint Fixation System**Oct 3, 2022  
178 days to decisionK221047 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k221047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Apr 8, 2022
Decision date	Oct 3, 2022
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aurora Spine, Inc.</b>
Location	Washington, DC, US
Contact	Laszlo Garamszegi
510(k) history	7 submissions · 7 cleared · 2014-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Samuel Pollard

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221047/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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