

**K200868 SI-Restore Sacroiliac Joint Fixation System**Apr 17, 2020  
16 days to decisionK200868 · Product code: **OUR** · Orthopedic  
Source: <https://www.510kdatabase.net/k200868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Apr 1, 2020
Decision date	Apr 17, 2020
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biofusion Medical</b>
Location	Austin, TX, US
Contact	Rylan Reed
510(k) history	2 submissions · 2 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Surgop Support</b>
Contact	Daniel Lanois

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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