

K181881 Outlet Sacroiliac Joint Fusion SystemOct 3, 2018
82 days to decisionK181881 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k181881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Jul 13, 2018
Decision date	Oct 3, 2018
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sij Surgical
Location	Raleigh, NC, US
Contact	Daniel Hoehn
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Empirical Consulting, LLC
Contact	Meredith L. May

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181881/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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