

K183342 SambaScrew 3D SI Fusion SystemApr 30, 2019
148 days to decisionK183342 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k183342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 3, 2018
Decision date	Apr 30, 2019
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix, Inc.
Location	Mckinney, TX, US
Contact	Jacki Koch
510(k) history	57 submissions · 57 cleared · 1996-2024

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