

K203780 Harvester SI: Sacroiliac Fixation SystemMar 23, 2021
85 days to decisionK203780 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k203780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 28, 2020
Decision date	Mar 23, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spinus International, Inc.
Location	Georgetown, TX, US
Contact	Ron Oman
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Empirical Testing Corp
Contact	Nathan Wright

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/k203780/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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