

K123702 SILEX SACROILIAC JOINT FUSION SYSTEM

Mar 11, 2013
98 days to decision

K123702 · Product code: **OUR** · Orthopedic
Source: <https://www.510kdatabase.net/k123702/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sacroiliac Joint Fixation (OUR)
Date received	Dec 3, 2012
Decision date	Mar 11, 2013
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	X-Spine Systems, Inc.
Location	Centerville, OH, US
Contact	DAVID KIRSCHMAN, M.D.
510(k) history	34 submissions · 34 cleared · 2005-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k123702/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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