

K123412 RANGE SPINAL SYSTEM, SMALL STRATURE COMPONENTS

Feb 13, 2013
99 days to decision

K123412 · Product code: **OSH** · Orthopedic
Source: <https://www.510kdatabase.net/k123412/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)
Date received	Nov 6, 2012
Decision date	Feb 13, 2013
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, Inc.
Location	Leesburg, VA, US
Contact	NANCY GIEZEN
510(k) history	100 submissions · 97 cleared · 2007-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k123412/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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