

K121630 RANGE SPINAL SYSTEMSep 11, 2012
99 days to decisionK121630 · Product code: **OSH** · Orthopedic
Source: <https://www.510kdatabase.net/k121630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis (OSH)
Date received	Jun 4, 2012
Decision date	Sep 11, 2012
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

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