

K153031 RANGE/DENALI/MESA Spinal SystemNov 17, 2015
29 days to decisionK153031 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k153031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 19, 2015
Decision date	Nov 17, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	K2m, Incorporated
Location	Leesburg, VA, US
Contact	NANCY GIEZEN
510(k) history	3 submissions · 3 cleared · 2015-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026