FDA 510(k) Premarket Notification

K153031 RANGE/DENALI/MESA Spinal System

CLEARED

Nov 17, 2015
29 days to decision

K153031 · 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