FDA 510(k) Premarket Notification

K131980 SEQUOIA PEDICLE SCREW SYSTEM INCLUDING SPEEDLINK II TRANSVERSE CONNECTOR SYSTEM

CLEARED

Sep 4, 2013
68 days to decision

K131980 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k131980/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jun 28, 2013
Decision date	Sep 4, 2013
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Spine, Inc.**
Location	Minneapolis, MN, US
Contact	JONATHAN GILBERT
510(k) history	38 submissions · 35 cleared · 2004-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k131980/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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