

K182598 VersaLink™ Fixation SystemNov 13, 2018
54 days to decisionK182598 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k182598/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 20, 2018
Decision date	Nov 13, 2018
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Premia Spine, Ltd.
Location	Ramat Poleg, IL
Contact	Ron Sacher
510(k) history	6 submissions · 6 cleared · 2015-2023

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