

K170061 ProMIS™ Fixation SystemFeb 2, 2017
27 days to decisionK170061 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k170061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jan 6, 2017
Decision date	Feb 2, 2017
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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