FDA 510(k) Premarket Notification

K150380 ProMIS Fixation System

CLEARED

Jul 17, 2015
154 days to decision

K150380 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k150380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Feb 13, 2015
Decision date	Jul 17, 2015
Days to decision	154 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