

K143377 PedFuse Pedicle Screw SystemFeb 12, 2015
79 days to decisionK143377 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k143377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Nov 25, 2014
Decision date	Feb 12, 2015
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spinefrontier, Inc.
Location	Beverly, MA, US
Contact	Manthan J Damani
510(k) history	24 submissions · 24 cleared · 2007-2020

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