

K123164 SPINEFRONTIER PEDFUSE PEDICLE SCREW SYSTEMFeb 15, 2013
129 days to decisionK123164 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k123164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Oct 9, 2012
Decision date	Feb 15, 2013
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spinefrontier, Inc.
Location	Beverly, MA, US
Contact	FREDY H VARELA
510(k) history	24 submissions · 24 cleared · 2007-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123164/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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