

K162419 FIREFLY® Pedicle Screw Navigation GuideOct 28, 2016
59 days to decisionK162419 · Product code: **PQC** · Orthopedic
Source: <https://www.510kdatabase.net/k162419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pedicle Screw Placement Guide (PQC)
Date received	Aug 30, 2016
Decision date	Oct 28, 2016
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mighty Oak Medical, Inc.
Location	Englewood, CO, US
Contact	Mark A. Wylie
510(k) history	5 submissions · 5 cleared · 2015-2022

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