

K132765 PFX SPINOUS PROCESS FIXATION SYSTEMJul 14, 2014
313 days to decisionK132765 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k132765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Sep 4, 2013
Decision date	Jul 14, 2014
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovasis, Inc.
Location	Salt Lake City, UT, US
Contact	MARSHALL MCCARTY
510(k) history	33 submissions · 32 cleared · 2004-2025

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