

K132411 AFFIX II SPINOUS PROCESS PLATE SYSTEMNov 20, 2013
110 days to decisionK132411 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k132411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Aug 2, 2013
Decision date	Nov 20, 2013
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nu Vasive, Incorporated
Location	San Diego, CA, US
Contact	OLGA LEWIS
510(k) history	112 submissions · 112 cleared · 2012-2023

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