

K143388 Affix IIS Spinous Process Plate SystemMar 5, 2015
99 days to decisionK143388 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k143388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Nov 26, 2014
Decision date	Mar 5, 2015
Days to decision	99 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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