

K133052 AFFIX(R) NEXT GEN SPINOUS PROCESS PLATE SYSTEMDec 20, 2013
84 days to decisionK133052 · Product code: **PEK** · Orthopedic
Source: <https://www.510kdatabase.net/k133052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spinous Process Plate (PEK)
Date received	Sep 27, 2013
Decision date	Dec 20, 2013
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nuvasive, Inc.
Location	San Diego, CA, US
Contact	OLGA LEWIS
Website	http://www.nuvasive.com/
510(k) history	91 submissions · 90 cleared · 1999-2024

NuVasive, Inc. is a medical device company headquartered in San Diego, California. The company develops and markets surgical solutions focused on spine and orthopedic procedures. NuVasive operates globally and serves healthcare professionals and patients worldwide. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Orthopedic devices represent the dominant category, accounting for the majority of the company's cleared submissions. The most recent clearance was granted in 2024, demonstrating continued r...