

K092287 NUVASIVE SPHERX II - PEDICLE SCREW SYSTEMOct 6, 2009
69 days to decisionK092287 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k092287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 29, 2009
Decision date	Oct 6, 2009
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nuvasive, Inc.
Location	San Diego, CA, US
Contact	Sheila Bruschi
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...