

K061778 NUVASIVE SPHERX II SYSTEMJul 18, 2006
22 days to decisionK061778 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k061778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Jun 26, 2006
Decision date	Jul 18, 2006
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nuvasive, Inc.
Location	San Diego, CA, US
Contact	LAETITIA COUSIN
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...
