FDA 510(k) Premarket Notification

K083028 MODIFICATION TO: NUVASIVE SPHERX II SYSTEM

CLEARED

Nov 13, 2008
34 days to decision

K083028 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k083028/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 10, 2008
Decision date	Nov 13, 2008
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nuvasive, Inc.**
Location	San Diego, CA, US
Contact	HAN FAN
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...

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Device record: https://www.510kdatabase.net/k083028/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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