FDA 510(k) Premarket Notification

K123307 NUVASIVE NVM5 SYSTEM

CLEARED

Apr 23, 2013
181 days to decision

K123307 · Product code: **PDQ** · Neurology
Source: https://www.510kdatabase.net/k123307/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurosurgical Nerve Locator (PDQ)
Date received	Oct 24, 2012
Decision date	Apr 23, 2013
Days to decision	181 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...