FDA 510(k) Premarket Notification

CLEARED

K002677 NUVASIVE INS-1 INTRAOPERATIVE NERVE SURVEILLANCE SYSTEM

Nov 13, 2000
77 days to decision

K002677 · Product code: **BXM** · Anesthesiology
Source: https://www.510kdatabase.net/k002677/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Ac-powered (BXM)
Date received	Aug 28, 2000
Decision date	Nov 13, 2000
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nuvasive, Inc.**
Location	San Diego, CA, US
Contact	R. STEPHEN REITZLER
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...