

K053581 NUVASIVE SMARTPLATE GRADIENT PLUS SYSTEMFeb 17, 2006
56 days to decisionK053581 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k053581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 23, 2005
Decision date	Feb 17, 2006
Days to decision	56 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...
