FDA 510(k) Premarket Notification

K071329 NUVASIVE HELIX ACP SYSTEM

CLEARED

Aug 8, 2007
89 days to decision

K071329 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k071329/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	May 11, 2007
Decision date	Aug 8, 2007
Days to decision	89 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...