

K083341 NUVASIVE HELIX-T ACP SYSTEMMar 20, 2009
128 days to decisionK083341 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k083341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Nov 12, 2008
Decision date	Mar 20, 2009
Days to decision	128 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...
