

**K013257 HEMI-ARC SURGICAL NAVIGATOR**Oct 30, 2001  
29 days to decisionK013257 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k013257/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Oct 1, 2001
Decision date	Oct 30, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nuvasive, Inc.</b>
Location	San Diego, CA, US
Contact	LAETITIA BERNARD
Website	<a href="http://www.nuvasive.com/">http://www.nuvasive.com/</a>
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...