

**K001323 NUVASIVE PERCUTANEOUS  
TRANSFACET/INTRAPEDICULAR SCREW**Jul 25, 2000  
90 days to decisionK001323 · Product code: MRW · Orthopedic  
Source: <https://www.510kdatabase.net/k001323/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Apr 26, 2000
Decision date	Jul 25, 2000
Days to decision	90 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...