

**K211757 Simplify Disc**Aug 20, 2021  
74 days to decisionK211757 · Product code: **QLQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k211757/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Instruments Designed For Use With Total Disc Replacement Devices (QLQ)
Date received	Jun 7, 2021
Decision date	Aug 20, 2021
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nuvasive, Inc.</b>
Location	San Diego, CA, US
Contact	Beth Neil
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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k211757/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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