

**K053215 SURGICAL MESH SYSTEM**Jul 17, 2006  
242 days to decisionK053215 · Product code: **FTL** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k053215/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 17, 2005
Decision date	Jul 17, 2006
Days to decision	242 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 COUSIN
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...