

**K111597 DISPOSABLE STIMULATING ELECTRODE**Oct 13, 2011  
127 days to decisionK111597 · Product code: **ETN** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k111597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Jun 8, 2011
Decision date	Oct 13, 2011
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nuvasive, Inc.</b>
Location	San Diego, CA, US
Contact	Sheila Bruschi
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...