

**K061365 CHECKPOINT WITH ACCUSTIM TECHNOLOGY**Jul 12, 2006  
57 days to decisionK061365 · Product code: **ETN** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k061365/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	May 16, 2006
Decision date	Jul 12, 2006
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ndi Medical, LLC</b>
Location	Cleveland, OH, US
Contact	JULIE GRILL
510(k) history	3 submissions · 3 cleared · 2006-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061365/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 5, 2026