

**K992439 NORODYN 8000 SEMG SYSTEM, ND-8000**Aug 13, 1999  
22 days to decisionK992439 · Product code: **HCC** · Neurology  
Source: <https://www.510kdatabase.net/k992439/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Biofeedback (HCC)
Date received	Jul 22, 1999
Decision date	Aug 13, 1999
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Myotronics-Noromed, Inc.</b>
Location	Tukwila, WA, US
Contact	FRAY ADIB
510(k) history	7 submissions · 7 cleared · 1999-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992439/> 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 18, 2026