

**K213188 Primary Relief**Jan 31, 2022  
124 days to decisionK213188 · Product code: **NHI** · Neurology  
Source: <https://www.510kdatabase.net/k213188/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	Sep 29, 2021
Decision date	Jan 31, 2022
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dyansys, Inc.</b>
Location	Orinda, CA, US
Contact	Srini Nageshwar
510(k) history	14 submissions · 14 cleared · 2007-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213188/> 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 May 26, 2026