

**K221376 Nalu Neurostimulation System**Jun 10, 2022  
29 days to decisionK221376 · Product code: **GZB** · Neurology  
Source: <https://www.510kdatabase.net/k221376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	May 12, 2022
Decision date	Jun 10, 2022
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Neuromodulation</b>
Location	Valencia, CA, US
Contact	Kaoru Lee Adair
510(k) history	9 submissions · 9 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221376/> 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 14, 2026