

**K211965 StimRouter Neuromodulation System**Feb 23, 2022  
244 days to decisionK211965 · Product code: **GZF** · Neurology  
Source: <https://www.510kdatabase.net/k211965/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF)
Date received	Jun 24, 2021
Decision date	Feb 23, 2022
Days to decision	244 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioness, Inc.</b>
Location	Valencia, CA, US
Contact	Sageev George
510(k) history	13 submissions · 13 cleared · 2011-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211965/> 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 27, 2026