

K190047 StimRouter Neuromodulation SystemOct 31, 2019
295 days to decisionK190047 · Product code: **GZF** · Neurology
Source: <https://www.510kdatabase.net/k190047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF)
Date received	Jan 9, 2019
Decision date	Oct 31, 2019
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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