

**K142432 StimRouter Lead Kit/StimRouter Surgical Tool
Kit/StimRouter Clinician Kit/StimRouter User Kit**

Feb 20, 2015
175 days to decision

K142432 · Product code: **GZF** · Neurology
Source: <https://www.510kdatabase.net/k142432/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Implanted (pain Relief) (GZF)
Date received	Aug 29, 2014
Decision date	Feb 20, 2015
Days to decision	175 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k142432/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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