

**K162407 L300 Go System**Jan 27, 2017  
151 days to decisionK162407 · Product code: **GZI** · Neurology  
Source: <https://www.510kdatabase.net/k162407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Aug 29, 2016
Decision date	Jan 27, 2017
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioness, Inc.</b>
Location	Valencia, CA, US
Contact	MERCEDES BAYANI
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/k162407/> 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