

**K103343 L300 PLUS SYSTEM (RIGHT, LEFT), L300 PLUS SYSTEM UPGRADE KIT (RIGHT, LEFT)**Apr 29, 2011  
165 days to decisionK103343 · Product code: **GZI** · Neurology  
Source: <https://www.510kdatabase.net/k103343/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Nov 15, 2010
Decision date	Apr 29, 2011
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioness, Inc.</b>
Location	Valencia, CA, US
Contact	ADELE SHOUSTAL
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/k103343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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