

K122784 NESS L300 SYSTEM KIT, LEF MODEL LG3-5100Dec 27, 2012
107 days to decisionK122784 · Product code: **GZI** · Neurology
Source: <https://www.510kdatabase.net/k122784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Sep 11, 2012
Decision date	Dec 27, 2012
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary
Other names	NESS L300 SYSTEM KIT, RIGHT MODEL LG3-5000; SMALL NESS L300 SYSTEM KIT, RIGHT

APPLICANT

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

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