CLEARED

K120853 NESS L300 SYSTEM KIT, LEFT, NESS L300 SYSTEM KIT, RIGHT, SMALL NESS L300 SYSTEM KIT, RIGHT, SMALL NESS L300 SYSTEM KIT,

Apr 20, 2012
30 days to decision

K120853 · Product code: **GZI** · Neurology
Source: https://www.510kdatabase.net/k120853/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Mar 21, 2012
Decision date	Apr 20, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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