FDA 510(k) Premarket Notification

K103343 L300 PLUS SYSTEM (RIGHT, LEFT), L300 PLUS SYSTEM UPGRADE KIT (RIGHT, LEFT)

CLEARED

Apr 29, 2011
165 days to decision

K103343 · Product code: **GZI** · Neurology
Source: https://www.510kdatabase.net/k103343/

SUBMISSION DETAILS

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

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