

K191587 L360 Thigh SystemSep 12, 2019
90 days to decisionK191587 · Product code: **GZI** · Neurology
Source: <https://www.510kdatabase.net/k191587/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Jun 14, 2019
Decision date	Sep 12, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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