CLEARED

K123636 H200 WIRELESS HAND REHABILITATION SYSTEM WITH OPTIONAL INTELLI-CONNECT EARPIECE TRIGGERING DEVICE

May 1, 2013
159 days to decision

K123636 · Product code: **GZI** · Neurology
Source: https://www.510kdatabase.net/k123636/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Nov 23, 2012
Decision date	May 1, 2013
Days to decision	159 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