

**K123636 H200 WIRELESS HAND REHABILITATION SYSTEM  
WITH OPTIONAL INTELLI-CONNECT EARPIECE TRIGGERING  
DEVICE**May 1, 2013  
159 days to decisionK123636 · Product code: **GZI** · Neurology  
Source: <https://www.510kdatabase.net/k123636/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123636/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026