

**K103738 H-WAVE**Jun 1, 2011  
161 days to decisionK103738 · Product code: **IPF** · Physical Medicine  
Source: <https://www.510kdatabase.net/k103738/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Dec 22, 2010
Decision date	Jun 1, 2011
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Electronic Waveform Laboratory, Inc.</b>
Location	Walker, MI, US
Contact	RYAN P HEANEY
510(k) history	6 submissions · 6 cleared · 1982-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103738/> 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 June 19, 2026