

**K012823 MODIFICATION TO HANDMASTER**Nov 14, 2001  
90 days to decisionK012823 · Product code: **GZI** · Neurology  
Source: <https://www.510kdatabase.net/k012823/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Aug 16, 2001
Decision date	Nov 14, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ness-Neuromuscular Electrical Stimulation Systems</b>
Location	Washington, DC, US
Contact	JONATHAN S HAHAN
510(k) history	7 submissions · 7 cleared · 2001-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012823/> 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 18, 2026