

**K083322 NEUROMETRIX BIOAMPLIFIER**May 27, 2009  
196 days to decisionK083322 · Product code: **GWL** · Neurology  
Source: <https://www.510kdatabase.net/k083322/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Nov 12, 2008
Decision date	May 27, 2009
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Neurometrix, Inc.</b>
Location	North Attleboro, MA, US
Contact	RAINER MAAS
510(k) history	18 submissions · 17 cleared · 1998-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083322/> 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