

**K151050 Pacifier Activated Lullaby (PAL®)**Dec 22, 2015  
246 days to decisionK151050 · Product code: **HCC** · Neurology  
Source: <https://www.510kdatabase.net/k151050/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Apr 20, 2015
Decision date	Dec 22, 2015
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Power Medical Devices, LLC</b>
Location	Delray Beach, FL, US
Contact	Patricia Palmer
510(k) history	1 submissions · 1 cleared · 2015-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151050/> 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 3, 2026