

**K161154 Smartpatch PNS MicroLead and Accessories,  
Smartpatch PNS Stimulator, Pads, and Accessories,  
Smartpatch PNS MicroLead and Introducer, Smartpatch PNS  
Pads, 4 Packs**Jul 23, 2016  
89 days to decisionK161154 · Product code: **NHI** · Neurology  
Source: <https://www.510kdatabase.net/k161154/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	Apr 25, 2016
Decision date	Jul 23, 2016
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Spr Therapeutics, LLC</b>
Location	Cleveland, OH, US
Contact	Kathryn Stager
510(k) history	2 submissions · 2 cleared · 2016-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161154/> 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 1, 2026