

**K251246 Sparrow Ascent**Aug 25, 2025  
125 days to decisionK251246 · Product code: **PZR** · Neurology  
Source: <https://www.510kdatabase.net/k251246/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percutaneous Nerve Stimulator For Opioid Withdrawal (PZR)
Date received	Apr 22, 2025
Decision date	Aug 25, 2025
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spark Biomedical, Inc.</b>
Location	Dallas, TX, US
Contact	Brent Croft
510(k) history	3 submissions · 3 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251246/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026