

**K100912 DISPOSABLE NERVE STIMULATING PROBE,  
BIPOLAR CONCENTRIC, DISPOSABLE NERVE STIMULATOR  
PROBE, BIPOLAR SIDE BY SIDE**Aug 19, 2010  
140 days to decisionK100912 · Product code: **GXZ** · Neurology  
Source: <https://www.510kdatabase.net/k100912/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle (GXZ)
Date received	Apr 1, 2010
Decision date	Aug 19, 2010
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kirwan Surgical Products, Inc.</b>
Location	Rockland, MA, US
Contact	KEVIN P PRARIO
510(k) history	18 submissions · 18 cleared · 1990-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100912/> 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 20, 2026