

**K033122 5000Z SYSTEM (OTC)**Aug 25, 2004  
330 days to decisionK033122 · Product code: **NUH** · Neurology  
Source: <https://www.510kdatabase.net/k033122/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Sep 30, 2003
Decision date	Aug 25, 2004
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prizm Medical, Inc.</b>
Location	Norcross, GA, US
Contact	CATHRYN N CAMBRIA
510(k) history	8 submissions · 6 cleared · 1994-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033122/> 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 5, 2026