

**K213622 Cionic Neural Sleeve NS-100**Feb 14, 2022  
90 days to decisionK213622 · Product code: **GZI** · Neurology  
Source: <https://www.510kdatabase.net/k213622/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Nov 16, 2021
Decision date	Feb 14, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cionic</b>
Location	San Francisco, CA, US
Contact	Mihai Ionescu
510(k) history	2 submissions · 2 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213622/> 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 May 26, 2026