

**K243828 CIONIC NEURAL SLEEVE (NS-200)**May 2, 2025  
140 days to decisionK243828 · Product code: **GZI** · Physical Medicine  
Source: <https://www.510kdatabase.net/k243828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Neuromuscular, External Functional (GZI)
Date received	Dec 13, 2024
Decision date	May 2, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cionic, Inc.</b>
Location	Scotts Valley, CA, US
Contact	Mihai Ionescu
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243828/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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