

**K203546 gammaCore Sapphire**Feb 12, 2021  
70 days to decisionK203546 · Product code: **PKR** · Neurology  
Source: <https://www.510kdatabase.net/k203546/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-invasive Vagus Nerve Stimulator - Headache (PKR)
Date received	Dec 4, 2020
Decision date	Feb 12, 2021
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Electrocore, Inc.</b>
Location	Basking Ridge, NJ, US
Contact	Mike Romaniw
510(k) history	4 submissions · 4 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203546/> 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