

K182369 gammaCore SapphireNov 27, 2018
88 days to decisionK182369 · Product code: **PKR** · Neurology
Source: <https://www.510kdatabase.net/k182369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-invasive Vagus Nerve Stimulator - Headache (PKR)
Date received	Aug 31, 2018
Decision date	Nov 27, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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