

K211856 gammaCore SapphireSep 10, 2021
86 days to decisionK211856 · Product code: **PKR** · Neurology
Source: <https://www.510kdatabase.net/k211856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-invasive Vagus Nerve Stimulator - Headache (PKR)
Date received	Jun 16, 2021
Decision date	Sep 10, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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