

K191830 gammaCore SapphireMar 26, 2020
261 days to decisionK191830 · Product code: **PKR** · Neurology
Source: <https://www.510kdatabase.net/k191830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-invasive Vagus Nerve Stimulator - Headache (PKR)
Date received	Jul 9, 2019
Decision date	Mar 26, 2020
Days to decision	261 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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