

K182311 CervellaMar 7, 2019
195 days to decisionK182311 · Product code: **QJQ** · Neurology
Source: <https://www.510kdatabase.net/k182311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Electrotherapy Stimulator To Treat Insomnia And/or Anxiety (QJQ)
Date received	Aug 24, 2018
Decision date	Mar 7, 2019
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Neurological Devices, LLC
Location	Carmel, IN, US
Contact	Bart Waclawik
510(k) history	1 submissions · 1 cleared · 2019-2019

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