

K192764 NeuroOne Cortical ElectrodeNov 26, 2019
57 days to decisionK192764 · Product code: **GYC** · Neurology
Source: <https://www.510kdatabase.net/k192764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	Sep 30, 2019
Decision date	Nov 26, 2019
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neuroone, Inc.
Location	Minnetonka, MN, US
Contact	Debra Kridner
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Debra J Kridner
Contact	Debra Kridner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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