

K173684 g.Estim PROMay 4, 2018
154 days to decisionK173684 · Product code: **GYC** · Neurology
Source: <https://www.510kdatabase.net/k173684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cortical (GYC)
Date received	Dec 1, 2017
Decision date	May 4, 2018
Days to decision	154 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	G.Tec Medical Engineering GmbH
Location	Schiedlberg, AT
Contact	Christoph Guger
510(k) history	6 submissions · 6 cleared · 2006-2020

REGULATORY CONSULTANT

Consulting firm	Tuv Sud America, Inc.
Contact	Olaf Teichert

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

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