

K253301 BraiN20® (BraiN20)Jun 27, 2026
271 days to decisionK253301 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k253301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Sep 29, 2025
Decision date	Jun 27, 2026
Days to decision	271 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Time IS Brain, S.L.
Location	Badalona, ES
Contact	Montserrat Gutiérrez de Dios
510(k) history	1 submissions · 1 cleared · 2026-2026

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