

K261604 Enobio Dx (Enobio Dx 8)Jun 13, 2026
30 days to decisionK261604 · Product code: **GWQ** · Neurology
Source: <https://www.510kdatabase.net/k261604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	May 14, 2026
Decision date	Jun 13, 2026
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary
Other names	Enobio Dx (Enobio Dx 20);Enobio Dx (Enobio Dx 32)

APPLICANT

Company	Neuroelectrics Barcelona S.L.U.
Location	Barcelona, ES
Contact	Ana Maiques
510(k) history	2 submissions · 2 cleared · 2017-2026

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