FDA 510(k) Premarket Notification

K162681 Enobio Wireless EEG

CLEARED

Jun 2, 2017
249 days to decision

K162681 · Product code: **GWQ** · Neurology
Source: https://www.510kdatabase.net/k162681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Sep 26, 2016
Decision date	Jun 2, 2017
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neuroelectrics Barcelona S.L.U.**
Location	Barcelona, ES
Contact	Anna Maiques
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k162681/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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