

K222101 PrismMar 17, 2023
242 days to decisionK222101 · Product code: **HCC** · Neurology
Source: <https://www.510kdatabase.net/k222101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biofeedback (HCC)
Date received	Jul 18, 2022
Decision date	Mar 17, 2023
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Graymatters Health , Ltd.
Location	Haifa, IL
Contact	Adar Shani
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222101/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026