

K201989 B4C SystemOct 8, 2021
448 days to decisionK201989 · Product code: **GWM** · Neurology
Source: <https://www.510kdatabase.net/k201989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Jul 17, 2020
Decision date	Oct 8, 2021
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Braincare Desenvolvimento E Inovacao Tecnologica S.A.
Location	Sao Carlos, BR
Contact	Arnaldo Betta
510(k) history	2 submissions · 2 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	Msquared Associates, Inc.
Contact	Connie Qiu

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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