

K240821 B4C System - Addition of new sensor model (BcSs-PICNIW-2000)

Jul 18, 2024
115 days to decision

K240821 · Product code: **GWM** · Neurology
Source: <https://www.510kdatabase.net/k240821/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Mar 25, 2024
Decision date	Jul 18, 2024
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Braincare Desenvolvimento E Inova??o Tecnol?gica S.A.
Location	S?o Carlos, BR
Contact	Arnaldo Betta
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k240821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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