

K182073 BcSs-PICNI-2000 SensorOct 17, 2019
442 days to decisionK182073 · Product code: **GWM** · Neurology
Source: <https://www.510kdatabase.net/k182073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Aug 1, 2018
Decision date	Oct 17, 2019
Days to decision	442 days
Third-party review	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

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