

K210572 Neurodyn V2.0, Neurodyn Aussie V2.0May 11, 2021
74 days to decisionK210572 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k210572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Feb 26, 2021
Decision date	May 11, 2021
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ibramed Equipamentos Medicos
Location	Aventura, FL, US
Contact	Fabio Alexandre Pinto
510(k) history	6 submissions · 6 cleared · 2012-2021

REGULATORY CONSULTANT

Consulting firm	United Regulatory, LLC
Contact	Rodrigo Abreu

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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