FDA 510(k) Premarket Notification

CLEARED

K210572 Neurodyn V2.0, Neurodyn Aussie V2.0

May 11, 2021
74 days to decision

K210572 · Product code: **IPF** · Physical Medicine
Source: 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