FDA 510(k) Premarket Notification

K220327 geko W-3

CLEARED

Mar 4, 2022
28 days to decision

K220327 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k220327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Feb 4, 2022
Decision date	Mar 4, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Firstkind Limited**
Location	West Boylston, MA, US
Contact	Neil Buckley
510(k) history	11 submissions · 11 cleared · 2014-2022

REGULATORY CONSULTANT

Consulting firm	**Heyer Regulatory Solutions, LLC**
Contact	Sheila Hemeon-Heyer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov