FDA 510(k) Premarket Notification

K212762 geko W-2

CLEARED

Nov 29, 2021
90 days to decision

K212762 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k212762/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Aug 31, 2021
Decision date	Nov 29, 2021
Days to decision	90 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

CLINICAL EVIDENCE - NCT02482038

Geko Venous Leg Ulcer Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	22 patients (actual)
Study sites	1 site
Condition studied	Venous Leg Ulcer
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 10, 2019
Sponsor	Firstkind Ltd (Industry)

Primary outcome

Ultra sound measurements of haemodynamics

Secondary outcome

Adverse event rate

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02482038