

**K220327 geko W-3**Mar 4, 2022  
28 days to decisionK220327 · Product code: **IPF** · Physical MedicineSource: <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	<b>Firstkind Limited</b>
Location	West Boylston, MA, US
Contact	Neil Buckley
510(k) history	11 submissions · 11 cleared · 2014-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Heyer Regulatory Solutions, LLC</b>
Contact	Sheila Hemeon-Heyer

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220327/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026