

K192746 MyoWorx TM20Oct 19, 2021
750 days to decisionK192746 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k192746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 30, 2019
Decision date	Oct 19, 2021
Days to decision	750 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Myoworx, Inc.
Location	Guelph, CA
Contact	Bert Oucharek
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Dp Distribution & Consulting, LLC
Contact	Darren Reeves

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192746/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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