

**K202148 E-Fit Infinity System (EF-2090 Controller and EF-100 Unit)**Aug 25, 2021  
387 days to decisionK202148 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k202148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Aug 3, 2020
Decision date	Aug 25, 2021
Days to decision	387 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fit-Pro , Ltd.</b>
Location	Budapest, HU
Contact	Janos Papp
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202148/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026