

**K134001 FIREFLY**May 15, 2014  
139 days to decisionK134001 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k134001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Dec 27, 2013
Decision date	May 15, 2014
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Firstkind Limited</b>
Location	West Boylston, MA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	11 submissions · 11 cleared · 2014-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k134001/> 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