

**K181199 Katalyst Mark 1 Muscle Stimulation System Model 2**Sep 20, 2018  
136 days to decisionK181199 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k181199/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	May 7, 2018
Decision date	Sep 20, 2018
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Katalyst, Inc.</b>
Location	Seattle, WA, US
Contact	Bjoern Woltermann
510(k) history	3 submissions · 3 cleared · 2017-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181199/> 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 June 28, 2026