

**K200382 BTL-703-2**Jan 6, 2021  
323 days to decisionK200382 · Product code: **NGX** · Physical Medicine  
Source: <https://www.510kdatabase.net/k200382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Feb 18, 2020
Decision date	Jan 6, 2021
Days to decision	323 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Btl</b>
Location	Malborough, MA, US
Contact	David Chmel
510(k) history	4 submissions · 4 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200382/> 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 27, 2026