

**K190038 Xbody Newave USA**Apr 5, 2019  
87 days to decisionK190038 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k190038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Jan 8, 2019
Decision date	Apr 5, 2019
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xbody Hungary Kft.</b>
Location	Budapest, HU
Contact	Peter Tar
Website	<a href="http://xbodyworld.com/">http://xbodyworld.com/</a>
510(k) history	3 submissions · 3 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190038/> 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