

**K182519 Miha Bodytec II**Jun 7, 2019  
267 days to decisionK182519 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k182519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered, For Muscle Conditioning (NGX)
Date received	Sep 13, 2018
Decision date	Jun 7, 2019
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Miha Bodytec GmbH</b>
Location	Gersthofen, DE
Contact	Juergen Decker
510(k) history	3 submissions · 3 cleared · 2019-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182519/> 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