

**K202653 Gymform Total ABS**Jan 15, 2021  
123 days to decisionK202653 · Product code: **NGX** · Physical MedicineSource: <https://www.510kdatabase.net/k202653/>**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 14, 2020
Decision date	Jan 15, 2021
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Well Brain International , Ltd.</b>
Location	Hong Kong, Sar China, CN
Contact	Victor K. Wai
510(k) history	4 submissions · 4 cleared · 2012-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Guangzhou Kinda Biological Technology Co., Ltd.</b>
Contact	Jet Li

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202653/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026