

**K213043 Levator Elite (Model LE9011)**Feb 25, 2022  
156 days to decisionK213043 · Product code: **IPF** · Physical Medicine  
Source: <https://www.510kdatabase.net/k213043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Sep 22, 2021
Decision date	Feb 25, 2022
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Dongdixin Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	Siping Yuan
510(k) history	25 submissions · 25 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213043/> 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 13, 2026