

**K250746 Magnetic Surgical System**Jun 7, 2025  
87 days to decisionK250746 · Product code: **PNL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250746/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Magnetic Surgical System (PNL)
Date received	Mar 12, 2025
Decision date	Jun 7, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Levita Magnetics International Corp</b>
Location	San Mateo, CA, US
Contact	Donielle Baudin
510(k) history	8 submissions · 7 cleared · 2016-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Domecus Consulting Services</b>
Contact	Cindy Domecus

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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