

**K221958 Flex-MI**Oct 21, 2022  
108 days to decisionK221958 · Product code: **IPF** · Physical Medicine  
Source: <https://www.510kdatabase.net/k221958/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Jul 5, 2022
Decision date	Oct 21, 2022
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Emsi, Inc.</b>
Location	Tampa, FL, US
Contact	Chad Sagnip
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Msquared Associates, Inc.</b>
Contact	Cherita James

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/k221958/> 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 26, 2026