

**K250376 ViVY**Nov 5, 2025  
268 days to decisionK250376 · Product code: **IMJ** · Physical Medicine  
Source: <https://www.510kdatabase.net/k250376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diathermy, Shortwave, For Use In Applying Therapeutic Deep Heat (IMJ)
Date received	Feb 10, 2025
Decision date	Nov 5, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Viatherm Therapeutics, LLC</b>
Location	Annapolis, MD, US
Contact	Maria Fattore
510(k) history	2 submissions · 2 cleared · 2018-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Graematter, Inc.</b>
Contact	Sharon Bishop

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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