

K251905 Normatec Elite HipSep 18, 2025
90 days to decisionK251905 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k251905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jun 20, 2025
Decision date	Sep 18, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	NormaTec Industries, LP
Location	Washington, DC, US
Contact	Steve Henderson
510(k) history	9 submissions · 9 cleared · 2012-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic, LLC
Contact	Matt Dryden

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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