

K220217 Normatec 3Feb 25, 2022
30 days to decisionK220217 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k220217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jan 26, 2022
Decision date	Feb 25, 2022
Days to decision	30 days
Third-party review	Yes
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	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220217/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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