FDA 510(k) Premarket Notification

K240122 Normatec Elite

CLEARED

Mar 21, 2024
65 days to decision

K240122 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k240122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jan 16, 2024
Decision date	Mar 21, 2024
Days to decision	65 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