FDA 510(k) Premarket Notification

K221666 Normatec Go

CLEARED

Jul 14, 2022
36 days to decision

K221666 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k221666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Jun 8, 2022
Decision date	Jul 14, 2022
Days to decision	36 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